Action	Plaintiff	Jurisdiction in Which the Matter was Filed	Complaint Filed
Angela Beck and Martin Beck v. Bayer Corporation, et al. No. 09-cv-01207	Beck	NDOH	5/27/2009
Patti Bradish and Gary Bradish v. Bayer Corporation, et al. No. 09-cv-01687	Bradish	NDOH	7/21/2009
Carla Leigh Brazzel v. Bayer Corporation, et al. No. 09-cv-01684	Brazzel	NDOH	7/21/2009
Gail Brinker and Kenneth Brinker v. Bayer Corporation, et al. No. 09-cv-01682	Brinker	NDOH	7/21/2009
Lauren Cathis v. Bayer Corporation, et al. No. 09-cv-01690	Cathis	NDOH	7/21/2009
Anne Marie Eakins and Jonathan Eakins v. Bayer Corporation, et al. No. 09-cv-01579	Eakins	NDOH	7/10/2009
Brenda Ellyson v. Bayer Corporation, et al. 09-cv-01687	Ellyson	NDOH	7/21/2009
Candace L. Fries Individually and as Administratrix of the Estate of Stephanie R. Hoover v. Bayer Corporation, et al. 09-cv-01085	Fries	NDOH	5/11/2009
Janet Gardner v. Bayer Corporation, et al. No. 09-cv-01980	Gardner	NDOH	8/24/2009
Kathy Johns and William Johns v. Bayer Corporation, et al. No. 09-cv-01685	Johns	NDOH	7/21/2009

Marie Clair Keultjes v. Bayer Corporation, et al. No. 09-cv-01659	Keultjes	NDOH	7/17/2009
Saretta Main and Christina Maniaci v. Bayer Corporation, et al. No. 09-cv-01688	Main and Maniaci	NDOH	7/21/2009
Heather Manion v. Bayer Corporation, et al. No. 09-cv-01750	Manion	NDOH	7/21/2009
Marlene Meadows v. Bayer Corporation, et al. No. 09-cv-01574	Meadows	NDOH	7/9/2009
Lauren L. Murphy v. Bayer Corporation, et al. 09-cv-01582	Murphy	NDOH	7/10/2009

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IN THE U.S. DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

ANGELA BECK
13125 Kay Street
Paulding, Ohio 45879

and

MARTIN BECK
13125 Kay Street
Paulding, Ohio 45879

Plaintiffs,

v.

BAYER CORPORATION
c/o CSC-Lawyers Incorporating Service (Corporation Service Company)
50 W. Broad St. Suite 1800
Columbus, OH 43215

and

BAYER HEALTHCARE LLC,
c/o CSC-Lawyers Incorporating Service (Corporation Service Company)
50 W. Broad St. Suite 1800
Columbus, OH 43215

and

BAYER PHARMACEUTICALS CORPORATION,
c/o CSC-Lawyers Incorporating Service (Corporation Service

CASE NO.

JUDGE

COMPLAINT WITH JURY DEMAND ENDORSED HEREON

David W. Zoll (0008548)
Michelle L. Kranz (0062479)
Pamela A. Borgess (0072789)
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Counsel for Plaintiffs

Company)
50 W. Broad St. Suite 1800
Columbus, OH 43215

and

BAYER HEALTHCARE
PHARMACEUTICALS INC.
c/o CSC-Lawyers Incorporating
Service (Corporation Service
Company)
50 W. Broad St. Suite 1800
Columbus, OH 43215

and

BERLEX LABORATORIES, INC.
c/o CSC-Lawyers Incorporating
Service (Corporation Service
Company)
340 Changebridge Road
Montville, NJ 07405

and

BERLEX, INC.
c/o CSC-Lawyers Incorporating
Service (Corporation Service
Company)
340 Changebridge Road
Montville, NJ 07405

and

BAYER SCHERING PHARMA AG
MÜLLERSTRASSE 178
13353 BERLIN, GERMANY

and

BAYER AG
BAYERWERK, GEBÄUDE W11,
KAISER-WILHELM-ALLEE
51368 LEVERKUSEN, GERMANY

and

JOHN DOE MANUFACTURERS A-Z [Real Names and Addresses Unknown]

and

JOHN DOE DISTRIBUTORS A-Z [Real Names and Addresses Unknown]

Defendants.

Now come Angela and Martin Beck, by and through the undersigned counsel, and for their Complaint hereby aver and state as follows:

NATURE OF THE ACTION

1. This is an action for strict product liability (Ohio R. C. §§ 2307.71-2307.80), fraud, civil conspiracy and commercial bribery, and punitive damages brought by Plaintiff for damages associated with her ingestion of the pharmaceutical drug YAZ, an oral contraceptive developed, designed, licensed, manufactured, distributed, sold, and/or marketed by Defendants.

2. As a result of the ingestion of YAZ, Plaintiff Angela Beck has suffered injuries to her person including, but not limited to, a pulmonary embolism.

THE PARTIES

3. Plaintiff Angela Beck, (herein "Plaintiff"), resides in the village of Paulding, Paulding County, Ohio.

4. Plaintiff is married to Plaintiff Martin Beck, who also resides in the village of Paulding, Paulding County, Ohio.

5. Defendant BAYER CORPORATION is, and at all times relevant was, a corporation organized under the laws of the State of Indiana with its headquarters and principal place of business at 100 Bayer Rd., Pittsburgh, Pennsylvania 15205.

6. At all times relevant, Defendant BAYER CORPORATION was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, YAZ.

7. Defendant BAYER HEALTHCARE LLC, is, and at times relevant was, a limited liability corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 100 Bayer Road, Pittsburg, PA 15205.

8. At all times relevant, Defendant BAYER HEALTHCARE LLC was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, YAZ.

9. Defendant BAYER HEALTHCARE LLC is wholly owned by Defendant BAYER CORPORATION.

10. Defendant BAYER PHARMACEUTICALS CORPORATION is, and at times relevant was, a corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 1400 Morgan Lane, West Haven, Connecticut.

11. At all times relevant, Defendant BAYER PHARMACEUTICALS CORPORATION was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, YAZ.

12. As of January 1, 2008, Defendant BAYER PHARMACEUTICALS CORPORATION was merged into Defendant BAYER HEALTHCARE PHARMACEUTICALS INC.

13. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC., is and at times relevant was, a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

14. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc., and is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc.

15. At all times relevant, Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, YAZ.

16. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. is the holder of approved New Drug Application ("NDA") for YAZ.

17. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. are, and at all times relevant were, foreign corporations with their headquarters and principal places of business at Montville, New Jersey and with a post office address of P.O. Box 1000, Montville, New Jersey, 07045 and places of business located at 6 West Belt Road, Wayne, New Jersey 07470.

18. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. were integrated into Bayer HealthCare AG and operates as an integrated specialty pharmaceuticals business under the new name, Defendant Bayer Healthcare Pharmaceuticals, Inc.

19. At all times relevant, Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, YAZ.

20. Defendant BAYER SCHERING PHARMA AG, formerly known as Schering AG, is a pharmaceutical company that is organized and existing under the laws of the Federal Republic of German, having a principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.

21. Defendant BAYER SCHERING PHARMA AG is a corporate successor to Schering AG.

22. Schering AG was renamed BAYER SCHERING PHARMA AG effective December 29, 2006.

23. Defendant BAYER SCHERING PHARMA AG'S headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205.

24. At all times relevant, Defendant BAYER SCHERING PHARMA AG was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, YAZ.

25. Defendant BAYER SCHERING PHARMA AG is the current owner of the patent(s) relating to the oral contraceptive, YAZ.

26. Defendant BAYER AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.

27. Defendant BAYER AG is the third largest pharmaceutical company in the world.

28. Defendant BAYER AG is the parent/holding company of all other named Defendants.

29. Defendant BAYER AG's headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205.

30. At all times relevant, Defendant BAYER AG was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, YAZ.

31. Defendants John Doe Manufacturers A-Z (fictitious-name designations of one or more individuals, partnerships, corporations, and/or other entities whose actual identities have yet to be determined) at all times relevant hereto were in the business of developing, researching, selling, distributing, designing, manufacturing, testing, evaluating, licensing, labeling, marketing, and/or placing, either directly or indirectly through third parties or related entities, pharmaceutical drugs including YAZ into interstate commerce, including in the Northern District of Ohio, and derived substantial revenue from these activities.

32. Defendants John Doe Distributors A-Z (fictitious-name designations of one or more individuals, partnerships, corporations, and/or other entities whose actual identities have yet to be determined) at all times relevant hereto were in the business of developing, researching, selling, distributing, designing, manufacturing, testing, evaluating, licensing, labeling, marketing, and/or placing, either directly or indirectly through third parties or

related entities, pharmaceutical drugs including YAZ into interstate commerce, including in the Northern District of Ohio, and derived substantial revenue from these activities.

33. Defendants Bayer Corporation, Bayer Healthcare LLC, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Berlex Laboratories, Inc. and Berlex, Inc., Bayer Schering Pharma AG, Bayer AG, John Doe Manufacturers and Distributors A-Z shall be referred to herein individually by name or jointly as "Defendants."

34. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

35. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in interest, aider and abettor, co-conspirator and joint venturer of each of the remaining Defendants herein and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture.

JURISDICTION AND VENUE

36. This Court has jurisdiction over this action pursuant to 28 U.S.C.A. § 1332, as there is complete diversity of citizenship between Plaintiff and Defendants, and the amount in controversy exceeds $75,000, exclusive of interest and costs.

37. Venue is proper in the Northern District of Ohio pursuant to 28 U.S.C.A. § 1391, as a substantial part of the events giving rise to these claims occurred within this district, including the prescription and use of YAZ, as well as Plaintiff's resulting injuries.

38. The Court has personal jurisdiction over Defendants consistent with the Ohio and United States Constitution pursuant to Ohio R. C. § 2307.382(4) because Defendants caused

tortious injury in Ohio by an act or omission outside Ohio by virtue of Defendants' regularly conducted business in Ohio from which they respectively derive substantial revenue. Defendants do substantial business in the State of Ohio and within the Northern District of Ohio, advertise in this district, and receive substantial compensation and profits from sales of YAZ within this District.

39. Defendants expected or should have expected that their business activities could or would have consequences within the State of Ohio, as well as throughout the United States.

FACTS

40. Yasmin, (a predecessor to YAZ), known generically as drospirenone and ethinyl estradiol, is a combination birth control pill originally developed by Defendant BERLEX LABORATORIES, INC. and/or Defendant BERLEX, INC containing the hormones estrogen and progestin.

41. The estrogen is ethinyl estradiol and the progestin is drospirenone, (3 mg of drospirenone and 0.03 mg of ethinyl estradiol per tablet).

42. Combination birth control pills are referred to as combined hormonal oral contraceptives.

43. Yasmin was approved by the FDA in April, 2001.

44. In 2006, Bayer acquired Defendant BERLEX LABORATORIES, INC. and/or Defendant BERLEX, INC, and began marketing an almost identical drug, YAZ (which contains 3 mg of drospirenone and 0.02 mg of ethinyl estradiol per tablet).

45. The difference between YAZ/Yasmin and other birth control pills on the market is that drospirenone has never before been marketed in the United States and is unlike other progestins available in the United States.

46. In April 2002, the British Medical Journal reported that the Dutch College of General

Practitioners recommended that older second generation birth control pills be prescribed in lieu of Yasmin as a result of 40 cases of venous thrombosis among women taking Yasmin.

47. In February 2003, a paper entitled *Thromboembolism Associated With the New Contraceptive Yasmin* was published in the British Medical Journal detailing a Netherlands Pharmacovigilance Centre report of five additional reports of thromboembolism where Yasmin was suspected as the cause, including two deaths.

48. Defendants have been warned at least three times by the FDA; in 2003, 2008 and 2009, for misleading the public through the use of ads which overstate the efficacy of YAZ and/or its predecessor Yasmin, and minimize serious risks associated with the drug.

49. The use of YAZ has a prothrombotic effect resulting in thrombosis such as the pulmonary embolism suffered by Plaintiff.

50. Defendants ignored the correlation between the use of YAZ and increased thrombosis formation despite the wealth of scientific information available.

51. Upon information and belief, Defendants knew or should have known about the correlation between the use of YAZ and a prothrombotic effect and still promoted, sold, advertised, and marketed the use of YAZ.

52. Defendants falsely and fraudulently represented to the medical and healthcare community, to Plaintiff, the FDA, and the public in general, that YAZ had been tested and was found to be safe and/or effective for its indicated use.

53. These false representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, dispense and/or purchase YAZ for

use as a contraceptive, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of Plaintiff.

54. Defendants knew and were aware or should have been aware that YAZ had not been sufficiently tested, was defective in its design and testing, and/or that it lacked adequate and/or sufficient warnings.

55. Defendants knew or should have known that YAZ had a potential to, could, and would cause severe and grievous injury and death to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

56. In representations to Plaintiff, her healthcare providers, and/or the FDA, Defendants also fraudulently concealed and intentionally omitted the following material information:

A. That YAZ is not as safe as other available contraceptives;

B. That the risks of adverse events with YAZ (drospirenone and ethinyl estradiol) was higher than those of other available contraceptives;

C. That the risks of adverse events with YAZ was not adequately tested and/or known by Defendants;

D. Plaintiff was put at risk of experiencing serious and dangerous side effects including, but not limited to, a pulmonary embolism, as well as other severe and personal injuries, physical pain, and mental anguish;

E. That patients needed to be monitored more regularly than normal while using YAZ; and

F. That YAZ was designed, tested, manufactured, marketed, produced, distributed and advertised negligently, defectively, fraudulently and improperly.

57. Defendants were under a duty to disclose to Plaintiff and her physicians, hospitals, healthcare providers and/or the FDA the defective nature of YAZ.

58. Defendants had sole access to material facts concerning the defective nature of the product

and its propensity to cause serious and dangerous side effects, and hence, cause damage to person who used YAZ, including Plaintiff.

59. Defendants made the misrepresentations and/or actively concealed information concerning the safety and efficacy of YAZ with the intention and specific desire that the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, would rely on such in selecting YAZ as a contraceptive.

60. Defendants made these misrepresentations and/or actively concealed information concerning the safety and efficacy of YAZ in their labeling, advertising, product inserts, promotional material or other marketing efforts.

61. The misrepresentations of and/or active concealment by Defendants were perpetuated directly and/or indirectly by Defendants, its sales representative, employees, distributors, agents and/or detail persons.

62. Defendants knew that Plaintiff, her healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding YAZ, as set forth herein.

63. The misrepresentations of and/or active concealment by Defendants constitute a continuing tort. Indeed, through Defendants' product inserts, Defendants continue to misrepresent the potential risks and serious side effects associated with the use of YAZ.

64. Moreover, Defendants had a post-sale duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, about the potential risks and serious side effects associated with the use of YAZ in a timely manner, yet they failed to provide such warning.

FACTS REGARDING PLAINTIFF ANGELA BECK

65. Plaintiff was first prescribed YAZ by her health care provider in approximately April of 2007.

66. Plaintiff justifiably relied on and/or was induced by the misrepresentations and/or active concealment of Defendants to purchase and ingest YAZ to her detriment.

67. As a result of using Defendants' product YAZ, a few months later in approximately the end of June, early July 2007, Plaintiff suffered serious and life-threatening side effects including but not limited to, a pulmonary embolism, as well as other severe and personal injuries, including future thromboembolic events, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses, the need for lifelong medical treatment, monitoring and/or medications, and the fear of developing any of the above named health consequences.

68. Plaintiff did not discover, nor did she have any reason to discover that her injury was a result of a defective drug and/or the wrongful conduct of Defendants, as set forth herein, until at least April of 2009.

CAUSES OF ACTION
Statutory Products Liability (R.C. § 2307.71-2307.80)

69. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

70. Defendants are manufacturers, as defined at Revised Code § 2307.71, and distributors, which designed, produced, created, made, constructed and/or assembled the drug, YAZ.

71. YAZ reached the ultimate users without substantial change in the condition it was sold.

72. The drug was defective due to inadequate warning or instruction pursuant to the provisions of Ohio Revised Code § 2307.76, in its design pursuant to the provisions of Ohio Revised

Code § 2307.75 and/or in its failure to conform, when it left the control of Defendants, to their representations, pursuant to the provisions of Ohio Revised Code § 2307.77.

73. Said defect was a result of Defendants' failures including, but not limited to:

A. Defendants' failure to include adequate warnings that would alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, of the potential risks and serious side effects of the drug;

B. Defendants' failure to adequately and properly test and inspect the drug before placing the drug on the market;

C. Defendants' failure to conduct sufficient testing and inspection of the drug which, if properly performed, would have shown that the drug had serious side effects, including, but not limited to, a pulmonary embolism, and other serious and life threatening side effects;

D. Defendants' failure to adequately warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff of the potential risks and other serious side effects associated with the drug, including, among other things, a pulmonary embolism and other serious and life threatening side effects;

E. Defendants' failure to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risks associated with the use of the drug;

F. Defendants' failure to recall and/or remove the drug from the stream of commerce despite the fact that Defendants knew or should have known of the defective and unreasonably dangerous nature of the drug, including the significant health risks associated with the use of the drug; and

G. Defendants' encouragement of misuse and overuse while failing to disclose the side effects of the drug to the medical, pharmaceutical and/or scientific communities, and users and/or consumers, including Plaintiff, in order to maximize profit from sales.

74. Plaintiff was using YAZ in the manner for which it was intended and/or in a reasonably foreseeable manner.

75. Plaintiff was not aware of and reasonably could not have discovered the dangerous nature of YAZ.

76. As a result of the foregoing acts and omissions, Plaintiff suffered serious and life-threatening side effects including but not limited to, a pulmonary embolism, as well as other severe and personal injuries, including future thromboembolic events, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses, the need for lifelong medical treatment, monitoring and/or medications, and the fear of developing any of the above named health consequences.

Fraud

77. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

78. Defendants having undertaken the manufacturing, marketing, prescription, dispensing, distribution and promotion of YAZ described herein, owed a duty not to deceive the public regarding its drug's safety and to provide accurate and complete information regarding the product.

79. Since the drug's approval and on multiple occasions to the present date, Defendants fraudulently misrepresented information in various forms of media (including, but not limited to, ad campaigns, television, internet, etc.) regarding their product's safety.

80. At the time of Defendants' fraudulent misrepresentations, Plaintiff was unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

81. Defendants breached their duties to Plaintiff by providing false, incomplete and misleading information regarding their product.

82. Defendants acted with deliberate intent to deceive and mislead Plaintiff, her medical providers, and the public.

83. Plaintiff reasonably relied upon Defendants' deceptive, inaccurate and fraudulent misrepresentations.

84. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff suffered serious and life-threatening side effects including but not limited to, a pulmonary embolism, as well as other severe and personal injuries, including future thromboembolic events, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses, the need for lifelong medical treatment, monitoring and/or medications, and the fear of developing any of the above named health consequences.

Civil Conspiracy and Commercial Bribery

85. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

86. Defendants committed civil conspiracy, commercial bribery and conspiracy to commit commercial bribery in that fiduciaries of Defendants knowingly and/or intentionally offered, conferred, or agreed to confer benefits, gifts, and/or gratuities or conspired to do the same upon physicians, pharmacists, and insurance companies for the purpose of enticing these entities to use the drug YAZ, and to convince their patients and others of the safety and effectiveness of YAZ.

Loss of Consortium

87. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

88. As a result of the foregoing acts and omissions, and the resulting injuries, including but not limited to, personal injuries, medical expenses, and pain and suffering sustained by Plaintiff,

Plaintiff Martin Beck has suffered the loss of companionship, society, services, and consortium of his wife.

Punitive Damages

89. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

90. Defendants engaged in fraudulent and malicious conduct towards the Plaintiff, her medical providers and the public, and thereby acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiff and the public.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against the Defendants, jointly and severally, as follows:

A. For an award of compensatory damages, including damages against Defendants and each of them for medical and hospital expenses, loss of income, loss of consortium, and other damages according to proof at trial in excess of $75,000;

B. For an award of punitive or exemplary damages against Defendants and each of them in excess of $75,000;

C. For reasonable attorneys' fees and costs;

D. For pre-judgment interest; and

E. For such further and other relief the court deems just, equitable, and proper.

Dated: May 26, 2009

Respectfully Submitted,

/s/David W. Zoll

David W. Zoll (0008548)
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Counsel for Plaintiffs

JURY DEMAND

Plaintiff hereby demands a trial by jury on all triable issues.

/s/David W. Zoll
David W. Zoll (0008548)

IN THE U.S. DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

PATTI BRADISH
3705 South Berkey-Southern
Swanton, OH 43558

and

GARY BRADISH
3705 South Berkey-Southern
Swanton, OH 43558

Plaintiffs,

v.

BAYER CORPORATION
c/o CSC-Lawyers Incorporating
Service (Corporation Service
Company)
50 W. Broad St. Suite 1800
Columbus, OH 43215

and

BAYER HEALTHCARE LLC,
c/o CSC-Lawyers Incorporating
Service (Corporation Service
Company)
50 W. Broad St. Suite 1800
Columbus, OH 43215

and

BAYER PHARMACEUTICALS CORPORATION,
c/o CSC-Lawyers Incorporating
Service (Corporation Service
Company)
50 W. Broad St. Suite 1800

CASE NO.

JUDGE

COMPLAINT WITH JURY DEMAND ENDORSED HEREON

David W. Zoll (0008548)
Michelle L. Kranz (0062479)
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Counsel for Plaintiffs

Columbus, OH 43215

and

BAYER HEALTHCARE PHARMACEUTICALS INC.
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340 Changebridge Road
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340 Changebridge Road
Montville, NJ 07045

and

JOHN DOE MANUFACTURERS A-Z
[Real Names and Addresses Unknown]

and

JOHN DOE DISTRIBUTORS A-Z
[Real Names and Addresses Unknown]

Defendants.

Now come Plaintiffs, by and through the undersigned counsel, and for their Complaint hereby aver and state as follows:

NATURE OF THE ACTION

1. This is an action for strict product liability (Ohio R.C. § 2307.71 *et seq.*), fraudulent misrepresentation, civil conspiracy and commercial bribery, loss of consortium, and punitive damages brought by Plaintiff for damages associated with her ingestion of the pharmaceutical drug YAZ, an oral contraceptive developed, designed, licensed, manufactured, distributed, sold, and/or marketed by Defendants.

2. As a result of the ingestion of YAZ, Plaintiff Patti Bradish suffered injuries to her person including, but not limited to, deep vein thrombosis and a pulmonary embolism in October of 2007.

THE PARTIES

3. Plaintiff Patti Bradish, (herein "Plaintiff"), resides in the village of Swanton, Lucas County, Ohio.

4. Plaintiff is married to Plaintiff Gary Bradish, who also resides in the village of Swanton, Lucas County, Ohio.

5. Defendant BAYER CORPORATION is, and at all times relevant was, a corporation organized under the laws of the State of Indiana with its headquarters and principal place of business at 100 Bayer Rd., Pittsburgh, Pennsylvania 15205.

6. At all times relevant, Defendant BAYER CORPORATION was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly

through third parties, subsidiaries or related entities, the oral contraceptive, YAZ and its predecessor, Yasmin.

7. Defendant BAYER HEALTHCARE LLC, is, and at times relevant was, a limited liability corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 100 Bayer Road, Pittsburg, PA 15205.

8. At all times relevant, Defendant BAYER HEALTHCARE LLC was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

9. Defendant BAYER HEALTHCARE LLC is wholly owned by Defendant BAYER CORPORATION.

10. Defendant BAYER PHARMACEUTICALS CORPORATION is, and at times relevant was, a corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 1400 Morgan Lane, West Haven, Connecticut.

11. At all times relevant, Defendant BAYER PHARMACEUTICALS CORPORATION was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

12. As of January 1, 2008, Defendant BAYER PHARMACEUTICALS CORPORATION was merged into Defendant BAYER HEALTHCARE PHARMACEUTICALS INC.

13. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC., is and at times relevant was, a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

14. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc., and is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc.

15. At all times relevant, Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

16. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. applied for and received U.S. marketing approval of Yasmin and YAZ by the FDA, and is the holder of approved New Drug Application ("NDA") for Yasmin and YAZ.

17. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. are, and at all times relevant were, foreign corporations with their headquarters and principal places of business at Montville, New Jersey and with a post office address of P.O. Box 1000, Montville, New Jersey, 07045 and places of business located at 6 West Belt Road, Wayne, New Jersey 07470.

18. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. were integrated into Bayer HealthCare AG and operates as an integrated specialty pharmaceuticals business under the new name, Defendant Bayer Healthcare Pharmaceuticals, Inc.

19. At all times relevant, Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

20. Defendants John Doe Manufacturers A-Z (fictitious-name designations of one or more individuals, partnerships, corporations, and/or other entities whose actual identities have yet to be determined) at all times relevant hereto were in the business of developing, researching, selling, distributing, designing, manufacturing, testing, evaluating, licensing, labeling, marketing, and/or placing, either directly or indirectly through third parties or related entities, pharmaceutical drugs including Yasmin and YAZ into interstate commerce, including in the Northern District of Ohio, and derived substantial revenue from these activities.

21. Defendants John Doe Distributors A-Z (fictitious-name designations of one or more individuals, partnerships, corporations, and/or other entities whose actual identities have yet to be determined) at all times relevant hereto were in the business of developing, researching, selling, distributing, designing, manufacturing, testing, evaluating, licensing, labeling, marketing, and/or placing, either directly or indirectly through third parties or related entities, pharmaceutical drugs including Yasmin and YAZ into interstate commerce, including in the Northern District of Ohio, and derived substantial revenue from these activities.

22. Defendants Bayer Corporation, Bayer Healthcare LLC, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Berlex Laboratories, Inc. and Berlex, Inc., and John Doe Manufacturers and Distributors A-Z shall be referred to herein individually by name or jointly as "Defendants."

23. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

24. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in interest, aider and abettor, co-conspirator and joint venturer of each of the remaining Defendants herein and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture.

JURISDICTION AND VENUE

25. This Court has jurisdiction over this action pursuant to 28 U.S.C.A. § 1332, as there is complete diversity of citizenship between Plaintiff and Defendants, and the amount in controversy exceeds $75,000, exclusive of interest and costs.

26. Venue is proper in the Northern District of Ohio pursuant to 28 U.S.C.A. § 1391, as a substantial part of the events giving rise to these claims occurred within this district, including the prescription and use of YAZ, as well as Plaintiff's resulting injuries.

27. The Court has personal jurisdiction over Defendants consistent with the Ohio and United States Constitution pursuant to Ohio R. C. § 2307.382(4) because Defendants caused tortious injury in Ohio by an act or omission outside Ohio by virtue of Defendants' regularly conducted business in Ohio from which they respectively derive substantial revenue. Defendants do substantial business in the State of Ohio and within the Northern District of Ohio, advertise in this district, and receive substantial compensation and profits from sales of Yasmin and YAZ within this District.

28. Defendants expected or should have expected that their business activities could or would have consequences within the State of Ohio, as well as throughout the United States.

FACTS

Yasmin and YAZ Background

29. Yasmin, (a predecessor to YAZ), known generically as drospirenone and ethinyl estradiol, is a combination birth control pill originally developed by Defendant BERLEX LABORATORIES, INC. and/or Defendant BERLEX, INC containing the hormones estrogen and progestin.

30. The estrogen is ethinyl estradiol and the progestin is drospirenone, (3 mg of drospirenone and 0.03 mg of ethinyl estradiol per tablet).

31. Combination birth control pills are referred to as combined hormonal oral contraceptives.

32. Yasmin was approved by the FDA in April, 2001.

33. In 2006, Bayer acquired Defendant BERLEX LABORATORIES, INC. and/or Defendant BERLEX, INC, and began marketing an almost identical drug, YAZ (which contains 3 mg of drospirenone and 0.02 mg of ethinyl estradiol per tablet).

34. The difference between YAZ/Yasmin and other birth control pills on the market is that drospirenone has never before been marketed in the United States and is unlike other progestins available in the United States.

35. Shortly after the introduction of combined oral contraceptives in the 1960s, doctors and researchers found that women using birth control pills had a higher risk of blood clots, heart attacks and strokes than women not using the pill. As a result, the various brands of birth control pills were reformulated to reduce the amounts of estrogen. As the amounts of estrogen levels

reduced, so too did the risk of blood clots, heart attacks and strokes.

36. During this time, new progestins were being developed, which became known as "second generation" progestins (e.g. lovenorgestrel). These second generation progestins, when combined with the lower amounts of the estrogen, ethinyl estradiol, helped to reduce the risk of blood clots, heart attacks and strokes and were considered safer for women.

37. During the 1990s, new "third generation" progestins were developed. Unfortunately, these "third generation" progestins (e.g. gestodene and desogestrel) have been associated with a greater risk of blood clots in the deep veins (deep vein thrombosis or "DVT") and lungs (pulmonary embolism or "PE"). As a result of this increased risk of blood clots, the FDA has required that products containing third generation progestins include a warning of the potentially increased risk of thrombosis.

38. Yasmin and YAZ contain the same estrogen component, ethinyl estradiol, that has been used in the lower dose birth control pills for decades.

39. However, drospirenone is a new type of progestin and is considered a "fourth generation" progestin. No other birth control pills contain drospirenone, except for a recently approved generic version of Yasmin and YAZ marketed under the trade name, Ocella.

40. Since drospirenone in birth control is new, there are not decades of data available to support its safe use as there are with second generation progestins. Studies that were done prior to FDA approval, however, indicate that drospirenone has certain effects that are different from those of traditional second generation progestins, and potentially more dangerous.

41. One possible mechanism of action is that drospirenone causes an increase in potassium levels in the blood, which can lead to a condition known as hyperkalemia if the potassium levels become too high.

42. Hyperkalemia can cause heart rhythm disturbances, such as extrasystolies, pauses or bradycardia. If left untreated, hyperkalemia can be fatal.

43. If hyperkalemia disrupts the normal heart rhythms, the flow of blood through the heart can be slowed to the point that it permits blood clots to form. Blood clots in the heart can then lead to heart attacks, or the clots can break off and travel to the lungs where they can cause pulmonary embolism, or can travel to the brain causing stroke.

44. Another effect is a substantially increased risk of gallbladder complications.

45. During the brief time that Yasmin and YAZ have been sold in the United States, hundreds of reports of injury and death have been submitted to the FDA in association with Defendants' products.

46. In April 2002, the British Medical Journal reported that the Dutch College of General Practitioners recommended that older second generation birth control pills be prescribed in lieu of Yasmin as a result of 40 cases of venous thrombosis among women taking Yasmin.

47. In February 2003, a paper entitled *Thromboembolism Associated With the New Contraceptive Yasmin* was published in the British Medical Journal detailing a Netherlands Pharmacovigilance Centre report of five additional reports of thromboembolism where Yasmin was suspected as the cause, including two deaths.

48. In fact, in less than a five-year period, from the first quarter of 2004 through the third quarter of 2008, over 50 reports of death among users of Yasmin and YAZ have been filed with the FDA.

49. These reports include deaths associated with cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism and stroke in women in their child bearing years.

50. Some deaths reported occurred in women as young as 17 years old.

51. Significantly, reports of elevated potassium levels are frequently included among the symptoms of those suffering death while using Yasmin or YAZ.

Defendants' Over-Promotion, Fraud and Failures Regarding Yasmin and YAZ

52. Defendants market Yasmin and YAZ as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits.

53. However, because Yasmin and YAZ contain the fourth generation progestin drospirenone, they present additional health risks not associated with other birth control pills.

54. Defendants have been warned at least three times by the FDA; in 2003, 2008 and 2009, for misleading the public through the use of ads which overstate the efficacy of YAZ and/or its predecessor Yasmin, and minimize serious risks associated with the drug.

55. Indeed, the FDA felt Defendants' over-promotion of YAZ was so severe that it required Bayer to run new TV advertisements to correct the previous misleading YAZ advertisements.

56. Bayer ultimately agreed to spend at least $20 million on corrective TV advertisements and to submit all YAZ advertisements to the FDA for advanced screening for the next six years.

57. Defendants ignored the correlation between the use of Yasmin and YAZ and increased thrombosis formation despite the wealth of scientific information available.

58. Upon information and belief, Defendants knew or should have known about the correlation between the use of Yasmin and YAZ and a prothrombotic effect and still promoted, sold, advertised, and marketed the use of Yasmin and YAZ.

59. Defendants falsely and fraudulently represented to the medical and healthcare community, to Plaintiff, the FDA, and the public in general, that Yasmin and YAZ had been tested and was found to be safe and/or effective for its indicated use.

60. These false representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, dispense and/or purchase Yasmin and YAZ for use as a contraceptive, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of Plaintiff.

61. Defendants knew and were aware or should have been aware that Yasmin and YAZ had not been sufficiently tested, was defective in its design and testing, and/or lacked adequate and/or sufficient warnings.

62. Defendants knew or should have known that Yasmin and YAZ had a potential to, could, and would cause severe and grievous injury and death to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate and/or down-played warnings.

63. In representations to Plaintiff, her healthcare providers, and/or the FDA, Defendants also fraudulently concealed and intentionally omitted the following material information:

a. That Yasmin/YAZ is not as safe as other available contraceptives;

b. That the risks of adverse events with Yasmin/YAZ (drospirenone and ethinyl estradiol) was higher than those of other available contraceptives;

c. That the risks of adverse events with Yasmin/YAZ was not adequately tested and/or known by Defendants;

d. Plaintiff was put at risk of experiencing serious and dangerous side effects including, but not limited to, deep vein thrombosis, pulmonary embolisms, as well as other severe and personal injuries, physical pain, and mental anguish;

e. That patients needed to be monitored more regularly than normal while using Yasmin/YAZ; and/or

f. That Yasmin/YAZ was designed, tested, manufactured, marketed, produced,

distributed and advertised negligently, defectively, fraudulently and improperly.

64. Defendants were under a duty to disclose to Plaintiff and her physicians, hospitals, healthcare providers and/or the FDA the defective nature of Yasmin and YAZ.

65. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to person who used Yasmin and YAZ, including Plaintiff.

66. Defendants made the misrepresentations and/or actively concealed information concerning the safety and efficacy of Yasmin and YAZ with the intention and specific desire that the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, would rely on such in selecting Yasmin and YAZ as a contraceptive.

67. Defendants made these misrepresentations and/or actively concealed information concerning the safety and efficacy of Yasmin and YAZ in their labeling, advertising, product inserts, promotional material or other marketing efforts.

68. The misrepresentations of and/or active concealment by Defendants were perpetuated directly and/or indirectly by Defendants, its sales representative, employees, distributors, agents and/or detail persons.

69. Defendants knew that Plaintiff, her healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Yasmin and YAZ, as set forth herein.

70. The misrepresentations of and/or active concealment by Defendants constitute a continuing tort. Indeed, through Defendants' product inserts, Defendants continue to misrepresent the potential risks and serious side effects associated with the use of Yasmin and YAZ.

71. Moreover, Defendants had a post-sale duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, about the potential risks and serious side effects associated with the use of YAZ in a timely manner, yet they failed to provide such warning.

FACTS REGARDING PLAINTIFF PATTI BRADISH

72. Plaintiff was prescribed YAZ by her health care provider.

73. Plaintiff justifiably relied on and/or was induced by the misrepresentations and/or active concealment of Defendants to purchase and ingest YAZ to her detriment.

74. As a result of using Defendants' product YAZ, in October of 2007, Plaintiff suffered serious and life-threatening side effects including but not limited to, deep vein thrombosis and a pulmonary embolism, as well as other severe and personal injuries, including future thromboembolic events, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses, the need for lifelong medical treatment, monitoring and/or medications, and the fear of developing any of the above named health consequences.

75. Plaintiff did not discover, nor did she have any reason to discover that her injury was a result of a defective drug and/or the wrongful conduct of Defendants, as set forth herein, until at least July of 2009.

CAUSES OF ACTION

COUNTS I-IV

Defective Manufacturing/Construction (R.C. § 2307.74)

Defective Design/Formulation (R.C. § 2307.75)

Defective Warning/Instruction (R.C. § 2307.76)

Defective Due to Nonconformity with Representation (R.C. § 2307.77)

76. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

77. At all times relevant to this action, Defendants were the manufacturers, as defined at Revised Code § 2307.71, and distributors, which designed, produced, created, made, constructed and/or assembled the drugs, Yasmin and YAZ, that were placed into the stream of commerce.

78. The Yasmin and YAZ birth control pills were expected to and did reach the ultimate users, including Plaintiff, without substantial change in the condition they were sold.

79. The Yasmin and YAZ birth control pills manufactured, designed, sold, distributed, supplied, promoted and/or place in the stream of commerce by Defendant were defective in their:

a. Manufacture and construction pursuant to the provisions of Ohio Revised Code § 2307.74;

b. Design pursuant to the provisions of Ohio Revised Code § 2307.75;

c. Inadequate warning or instruction pursuant to the provisions of Ohio Revised Code § 2307.76, and/or

d. Failure to conform, when it left the control of Defendants, to their representations, pursuant to the provisions of Ohio Revised Code § 2307.77.

80. Specifically, Defendants' failures, which permitted defective drugs, Yasmin and YAZ, to be placed in the stream of commerce, include, but are not necessarily limited to:

a. Defendants' failure to exercise reasonable care in the manufacture, design and testing of Yasmin and YAZ;

b. Defendants' failure to include adequate warnings that would alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, of the substantially increased risks and serious side effects of the drug;

c. Defendants' failure to adequately and properly test and inspect the drug before placing the drug on the market;

d. Defendants' failure to conduct sufficient testing and inspection of the drug which, if properly performed, would have shown that the drug had serious increased side

effects, including, but not limited to, deep vein thrombosis, pulmonary embolism, and other serious and life threatening side effects;

e. Defendants' failure to adequately warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff of the potential risks and other serious side effects associated with the drug, including, among other things, deep vein thrombosis, pulmonary embolism and other serious and life threatening side effects;

f. Defendants' failure to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risks associated with the use of the drug;

g. Defendants' failure to recall and/or remove the drug from the stream of commerce despite the fact that Defendants knew or should have known of the defective and unreasonably dangerous nature of the drug, including the significant health risks associated with the use of the drug; and

h. Defendants' encouragement of misuse and overuse while failing to disclose the side effects of the drug to the medical, pharmaceutical and/or scientific communities, and users and/or consumers, including Plaintiff, in order to maximize profit from sales.

81. Yasmin and YAZ were unsafe for normal or reasonably anticipated use.

82. Plaintiff was using the drug in the manner for which it was intended and/or in a reasonably foreseeable manner.

83. Plaintiff could not, through the exercise of reasonable care, have discovered the defects or perceived the dangers posed by the drug.

84. As a direct and proximate result of this defective product, Plaintiff has been injured and incurred substantial damages, including, but not limited to, deep vein thrombosis and a pulmonary embolism, as well as other severe and personal injuries, including future thromboembolic events, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses, the need for lifelong medical treatment, monitoring and/or medications, and the fear of developing any of the above named health consequences.

85. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to recover punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

COUNT V
Fraudulent Misrepresentation

86. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows.

87. Defendants, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and promotion of Yasmin and YAZ, owed a duty not to deceive the Plaintiff, her health care providers and the public regarding the character, safety, quality and/or effectiveness of their drug.

88. The duty not to deceive is distinct from than the duty to warn and thus, was not abrogated by the Ohio Product Liability Act found at Ohio R.C. § 2307.71 *et seq*.

89. Since the drug's approval in April of 2001, and on multiple occasions to the present date, Defendants fraudulently misrepresented and published information in various forms of media (including, but not limited to, ad campaigns, television, internet, etc.) regarding their product's character, safety, quality and/or effectiveness, including, but not limited to, the public ad campaigns which were the subject of the FDA's 2003, 2008 and 2009 warnings.

90. At the time of Defendants' fraudulent misrepresentations, Plaintiff was unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

91. Defendants breached their duties to Plaintiff by providing false, incomplete and misleading information regarding Yasmin and YAZ.

92. Defendants acted with deliberate intent to deceive and mislead Plaintiff, her medical providers, and the public.

93. Plaintiff reasonably relied upon Defendants' deceptive, inaccurate and fraudulent misrepresentations.

94. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff suffered serious and life-threatening side effects including but not limited to, deep vein thrombosis and a pulmonary embolism, as well as other severe and personal injuries, including future thromboembolic events, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses, the need for lifelong medical treatment, monitoring and/or medications, and the fear of developing any of the above named health consequences.

95. Defendants' conduct was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety to patients/consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

COUNTS VI-VII
Civil Conspiracy and Commercial Bribery

96. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

97. Defendants committed civil conspiracy, commercial bribery and conspiracy to commit commercial bribery in that fiduciaries of Defendants knowingly and/or intentionally offered, conferred, or agreed to confer benefits, gifts, and/or gratuities or conspired to do the same upon physicians, pharmacists, and insurance companies for the purpose of enticing these

entities to use the drugs Yasmin and YAZ, and to convince their patients and others of the safety and effectiveness of Yasmin and YAZ.

COUNT VIII
Loss of Consortium

98. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

99. As a result of the foregoing acts and omissions, and the resulting injuries, including but not limited to, personal injuries, medical expenses, and pain and suffering sustained by Plaintiff, Plaintiff Gary Bradish has suffered the loss of companionship, society, services, and consortium of his wife.

COUNT IX
Punitive Damages

100.Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

101.Defendants engaged in fraudulent and malicious conduct towards the Plaintiff, her medical providers and the public, and thereby acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiff and the public.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendants, jointly and severally, as follows:

A. For an award of compensatory damages, including damages against Defendants and each of them for wrongful death, medical and hospital expenses, loss of income, loss of consortium, and other damages according to proof at trial in excess of $75,000;

B. For an award of punitive or exemplary damages against Defendants and each of them in excess of $75,000;

C. For reasonable attorneys' fees and costs;

D. For pre-judgment interest; and

E. For such further and other relief the court deems just, equitable, and proper.

Dated: July 21, 2009

Respectfully Submitted,

/s/David W. Zoll
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Counsel for Plaintiffs

JURY DEMAND

Plaintiff hereby demands a trial by jury on all triable issues.

/s/David W. Zoll
David W. Zoll (0008548)

IN THE U.S. DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

CARLA LEIGH BRAZZEL, 127 W. Chase Drive, West Monroe, Louisiana 71291, Plaintiff, v. **BAYER CORPORATION; BAYER HEALTHCARE, LLC; BAYER PHARMACEUTICALS CORPORATION; BAYER HEALTHCARE PHARMACEUTICALS, INC., BERLEX LABORATORIES, INC., BERLEX, INC.; BAYER SCHERING PHARMA AG; and BAYER AG,** Defendants.	Civil Action No. _____ **COMPLAINT WITH JURY DEMAND ENDORSED HEREON** David W. Zoll (0008548) Pamela A. Borgess (0072789) ZOLL, KRANZ & BORGESS, LLC 6620 W. Central Ave., Suite 200 Toledo, OH 43617 (419) 841-9623 Fax: (419) 841-9719 Email: david@toledolaw.com pamela@toledolaw.com Daniel N. Gallucci (Pa. 81995) Joanne E. Matusko (Pa. 91059) RODANAST, P.C. 801 Estelle Drive Lancaster, PA 17601 (717) 892-3000 Fax: (717) 892-1200 Email: dgallucci@rodanast.com jmatusko@rodanast.com *Counsel for Plaintiff*

COMPLAINT

NOW COMES Plaintiff for her multiple causes of action against Defendants and alleges and states the following:

THE PARTIES

1. Plaintiff Carla Leigh Brazzel ("Plaintiff") resides in West Monroe, Louisiana.

2. Plaintiff was prescribed and ingested YAZ and/or YASMIN and suffered injury, including, but not limited to, the development of a deep vein thrombosis.

3. Defendant BAYER CORPORATION is, and at all times relevant was, a corporation organized under the laws of the State of Indiana with its headquarters and principal place of business at 100 Bayer Rd., Pittsburgh, Pennsylvania 15205.

4. Defendant BAYER HEALTHCARE LLC, is, and at times relevant was, a limited liability corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 100 Bayer Road, Pittsburgh, PA 15205.

5. Defendant BAYER HEALTHCARE LLC is wholly owned by Defendant BAYER CORPORATION.

6. Defendant BAYER PHARMACEUTICALS CORPORATION is, and at times relevant was, a corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 1400 Morgan Lane, West Haven, Connecticut.

7. As of January 1, 2008, Defendant BAYER PHARMACEUTICALS CORPORATION was merged into Defendant BAYER HEALTHCARE PHARMACEUTICALS INC.

8. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC., is and at times relevant was, a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

9. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc., and is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc.

10. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. is the holder of approved New Drug Application ("NDA") for YAZ.

11. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. is the holder of approved New Drug Application ("NDA") for YASMIN.

12. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. are, and at all times relevant were, foreign corporations with their headquarters and principal places of business at Montville, New Jersey and with a post office address of P.O. Box 1000, Montville, New Jersey, 07045 and places of business located at 6 West Belt Road, Wayne, New Jersey 07470.

13. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. were integrated into Bayer HealthCare AG and operate as an integrated specialty pharmaceuticals business under the new name, Defendant Bayer Healthcare Pharmaceuticals, Inc.

14. Defendant BAYER SCHERING PHARMA AG, formerly known as Schering AG, is a pharmaceutical company that is organized and existing under the laws of

the Federal Republic of German, having a principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.

15. Defendant BAYER SCHERING PHARMA AG is a corporate successor to Schering AG.

16. Schering AG was renamed BAYER SCHERING PHARMA AG effective December 29, 2006.

17. Defendant BAYER SCHERING PHARMA AG'S headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205.

18. Defendant BAYER SCHERING PHARMA AG is the current owner of the patent(s) relating to the oral contraceptive, YASMIN.

19. Defendant BAYER SCHERING PHARMA AG is the current owner of the patent(s) relating to the oral contraceptive, YAZ.

20. Defendant BAYER AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.

21. Defendant BAYER AG is the third largest pharmaceutical company in the world.

22. Defendant BAYER AG is the parent/holding company of all other named Defendants.

23. Defendant BAYER AG's headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205.

24. Defendants Bayer Corporation, Bayer Healthcare LLC, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Berlex Laboratories, Inc. and Berlex, Inc., Bayer Schering Pharma AG, and Bayer AG, shall be referred to herein individually by name or jointly as "Defendants."

25. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

26. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in interest, aider and abettor, co-conspirator and joint venturer of each of the remaining Defendants herein and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture.

27. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptives, YAZ and YASMIN.

JURISDICTION AND VENUE

28. Plaintiff alleges damages in excess of one hundred fifty thousand dollars ($150,000.00), exclusive of costs and interests.

29. This Court has jurisdiction over this action pursuant to 28 U.S.C.A. § 1332, as there is complete diversity of citizenship between Plaintiff and Defendants, and the amount in controversy exceeds $150,000.00, exclusive of interest and costs.

30. Venue is proper in the Northern District of Ohio pursuant to 28 U.S.C.A. §1391, as a substantial part of the events or omissions giving rise to the claim occurred within this District, including, but not limited to, the development, design, licensing, labeling, manufacturing and/or marketing of the defective drug, as well as Defendant's fraud and conspiracy to actively concealed and/or misrepresent information concerning the safety and efficacy of YASMIN and YAZ with the intention and specific desire to mislead the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff.

FACTUAL BACKGROUND

31. Plaintiff took YAZ and/or YASMIN.

32. Plaintiff suffered serious personal injuries caused by YAZ and/or YASMIN, including, but not limited to, the development of a deep vein thrombosis.

33. At all relevant times, Defendants designed, manufactured, marketed, and distributed the pharmaceutical drugs YAZ and YASMIN, both which are oral contraceptives.

34. YASMIN received FDA approval first in 2001. It is a combination of drospirenone, a progestin, and ethinyl estradiol, an estrogen.

35. YAZ received approval from the FDA in 2006 and is essentially the same as YASMIN, with the only difference being a slightly smaller amount of ethinyl estradiol.

36. YAZ/YASMIN are indicated for the prevention of pregnancy in women who elect to use an oral contraceptive.

37. Combination birth control pills are referred to as combined hormonal oral contraceptives.

38. The difference between YASMIN/YAZ and other birth control pills on the market is that drospirenone has never before been marketed in the United States and is unlike other progestins available in the United States.

39. YAZ/YASMIN's use of drospirenone, a diuretic, creates unique risks compared to other oral contraceptives and is known to cause problems with the development of pulmonary embolism and deep vein thrombosis.

40. Upon information and belief, Defendants knew or should have known about the correlation between the use of YASMIN and YAZ and the significantly increased risk of the development of pulmonary embolism and deep vein thrombosis.

41. Yet, despite the wealth of scientific information available, Defendants ignored the correlation between the use of YASMIN and YAZ and the significantly increased risk of the development of pulmonary embolism and deep vein thrombosis and still promoted, sold, advertised, and marketed the use of YAZ/YASMIN without sufficient warnings.

42. Defendants have been warned at least three times by the FDA, in 2003, 2008 and 2009, for misleading the public through the use of ads which overstate the efficacy of YASMIN and YAZ, and minimize serious risks associated with the drug.

43. Defendants did not provide adequate warnings to doctors, the health care community and the public about the risk of serious adverse events that are described in this complaint.

44. As a result of the manufacture, marketing, advertising, promotion, distribution, the sale of YAZ/YASMIN without adequate warnings about the risks of serious injuries, Plaintiff has sustained severe and permanent personal injuries.

FACTS REGARDING PLAINTIFF CARLA LEIGH BRAZZEL

45. Plaintiff justifiably relied on and/or was induced by the misrepresentations and/or active concealment of Defendants to purchase and ingest YASMIN and/or YAZ to her detriment.

46. As a result of using Defendants' product YASMIN and/or YAZ, on or about July 28, 2008 Plaintiff suffered serious and life-threatening side effects including but not limited to, the development of a deep vein thrombosis, as well as other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses, the need for ongoing medical treatment, monitoring and/or medications, and the fear of developing other health consequences.

47. Plaintiff did not discover, nor did she have any reason to discover that her injury was a result of a defective drug and/or the wrongful conduct of Defendants, as set forth herein, until at least April of 2009.

CAUSES OF ACTION

COUNT I
FRAUDULENT CONCEALMENT

48. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

49. Prior to Plaintiff's use of YAZ/YASMIN and during the period in which Plaintiff actually used YAZ/YASMIN, Defendants fraudulently suppressed material information regarding the safety and efficacy of YAZ/YASMIN, including information regarding increased adverse events, pre and post marketing deaths, a high rate of severe adverse event reports compared to other birth control pills, and the unique gallbladder dangers. Furthermore, Defendants fraudulently concealed the safety information about the use of drospirenone, the only birth control pill using this ingredient. As described above, drospirenone has several well known serious side effects that are not seen in other forms of birth control. Plaintiff believes that the fraudulent misrepresentation described herein was intentional to keep the sales volume of YAZ/YASMIN strong.

50. Defendants fraudulently concealed safety issues with YAZ/YASMIN in order to induce physicians to prescribe and patients, including Plaintiff, to purchase and use YAZ/YASMIN.

51. At the time Defendants concealed the fact that YAZ/YASMIN was not safe, Defendants were under a duty to communicate this information to physicians, the FDA, the Healthcare community, and the general public in such a manner that they could appreciate the risks associated with using YAZ/YASMIN.

52. Plaintiff and the Plaintiff's prescribing doctor relied upon the Defendants' outrageous untruths regarding the safety of YAZ/YASMIN.

53. As a direct and proximate result of Defendants' malicious and or intentional concealment of material life altering information from Plaintiff and Plaintiff's prescribing doctor, Defendants caused or contributed to Plaintiff's injuries.

54. It is unconscionable and outrageous that Defendants would risk the lives of consumers. Despite this knowledge, the Defendants made conscious decisions not to redesign, label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct rises to the level necessary that Plaintiff should be awarded punitive damages to deter Defendants from this type of outrageous conduct in the future and to discourage Defendants from placing profits above the safety of patients in the United States of America.

55. Defendants' fraudulent concealment tolled the statute of limitations because only Defendants knew the true dangers associated with the use of YAZ/YASMIN as described herein. Defendants did not disclose this information to the Plaintiff, the prescribing doctor, the Healthcare community and the general public. Without full knowledge of the dangers of YAZ/YASMIN, Plaintiff and

Plaintiff's lawyer could not evaluate whether a person who was injured by YAZ/YASMIN had a valid claim.

WHEREFORE, Plaintiff demands judgment against Defendants for such compensatory damages and punitive damages as a jury may determine to be appropriate and necessary, in excess of the jurisdictional requirements of this Court, plus interest and costs.

COUNT II
STRICT LIABILITY

56. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

57. At the time of Plaintiff's injury, Defendants' pharmaceutical, YAZ/YASMIN, was defective and unreasonably dangerous to foreseeable consumers, including Plaintiff.

58. The YAZ/YASMIN used by Plaintiff was in the same or substantially similar condition as it was when it left the possession of Defendants.

59. Plaintiff did not misuse or materially alter the YAZ/YASMIN.

60. Defendants are strictly liable for Plaintiff's injury in the following ways:

a. The pharmaceutical YAZ/YASMIN as designed, manufactured, sold and/or supplied by the Defendants, was defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

b. Defendants failed to properly market, design, manufacture, distribute, supply and sell YAZ/YASMIN;

c. Defendants failed to warn and/or place adequate warnings and instructions on YAZ/YASMIN;

d. Defendants failed to adequately test YAZ/YASMIN;

e. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury associated with the use of YAZ/YASMIN; and

f. A feasible alternative design existed that was capable of preventing Plaintiff's injury.

61. Defendants' actions and omissions were the direct and proximate cause of Plaintiff's injury.

62. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants in an amount in excess of $150,000.00, plus delay damages, interest, costs and punitive damages.

COUNT III
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

63. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

64. At the time Defendants marketed, distributed and sold YAZ/YASMIN to Plaintiff, Defendants warranted that YAZ/YASMIN was merchantable and fit for the ordinary purposes for which it was intended.

65. Members of the consuming public, including consumers such as Plaintiff, were intended third party beneficiaries of the warranty.

66. YAZ/YASMIN was not merchantable and fit for its ordinary purpose, because it has a propensity to lead to the serious personal injuries described in this complaint.

67. Plaintiff reasonably relied on Defendants' representations that YAZ/YASMIN was safe and free of defects and was a safe means of birth control.

68. Defendants' breach of the implied warranty of merchantability was the direct and proximate cause of Plaintiff's injury.

69. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants in an amount in excess of $150,000.00, plus delay damages, interest, costs and punitive damages.

COUNT IV

BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

70. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

71. Defendants sold YAZ/YASMIN with an implied warranty that it was fit for the particular purpose of safe birth control, which offered other benefits, such as reduced bloating, reduced mood swings, improved complexion, and reduced the severity of women's menstruation.

72. Members of the consuming public, including Plaintiff, were intended third party beneficiaries of the warranty.

73. YAZ/YASMIN was not fit for the particular purpose of a safe birth control pill without serious risk of personal injury, which risk is much higher than other birth control pills.

74. Plaintiff reasonably relied on Defendants' representations that YAZ/YASMIN was safe and effective for use as a birth control method.

75. Defendants' breach of the implied warranty of fitness for a particular purpose was the direct and proximate cause of Plaintiff's injury.

76. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including

Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants in an amount in excess of $150,000.00, plus delay damages, interest, costs as allowed by law and punitive damages.

COUNT V
NEGLIGENT FAILURE TO WARN

77. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

78. Before Plaintiff used YAZ/YASMIN, and during the period in which she used it, Defendants knew or had reason to know that YAZ/YASMIN was dangerous and created an unreasonable risk of bodily harm to consumers.

79. Defendants had a duty to exercise reasonable care to warn end users of the dangerous conditions or of the facts that made YAZ/YASMIN likely to be dangerous.

80. Despite the fact that Defendants knew or had reason to know that YAZ/YASMIN was dangerous, Defendants failed to exercise reasonable care in warning the medical community and consumers, including Plaintiff, of the dangerous conditions and facts that made YAZ/YASMIN likely to be dangerous.

81. The Plaintiff's injury was a direct and proximate result of Defendants' failure to warn of the dangers of YAZ/YASMIN.

82. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants in an amount in excess of $150,000.00, plus delay damages, interest, costs and punitive damages.

COUNT VI
NEGLIGENCE

83. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

84. Defendants had a duty to exercise reasonable care in the manufacture, sale and distribution of YAZ/YASMIN, including a duty to assure that the product did not cause unreasonable, dangerous side effects to users.

85. Defendants failed to exercise ordinary care in the manufacture, sale, warnings, quality assurance, quality control, and distribution of YAZ/YASMIN in that Defendants knew or should have known that the drug created a high risk of unreasonable harm.

86. Defendants were negligent in the design, manufacture, advertising, warning, marketing and sale of YAZ/YASMIN in that, among other things, they:

a. Failed to use due care in designing and manufacturing YAZ/YASMIN so as to avoid the aforementioned risks to individuals;

b. Failed to accompany the drug with proper warnings regarding all possible adverse side effects associated with its use, and the comparative severity and duration of such adverse effects. The warnings given did not reflect accurately the symptoms, scope or severity of the side effects;

c. Failed to provide adequate training and instruction to medical care providers for appropriate use of YAZ/YASMIN;

d. Placed an unsafe product into the stream of commerce; and

e. Were otherwise careless or negligent.

87. Despite the fact that Defendants knew or should have known that YAZ/YASMIN caused unreasonable, dangerous side effects which many users would be unable to remedy by any means, Defendants continued to market YAZ/YASMIN to consumers, including the medical community and Plaintiff.

88. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with the knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants in an amount in excess of $150,000.00, plus delay damages, interest, costs and punitive damages.

COUNT VII
NEGLIGENT MISREPRESENTATION

89. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

90. Prior to Plaintiff first using YAZ/YASMIN and during the period in which she used YAZ/YASMIN, Defendants misrepresented that YAZ/YASMIN was a safe and effective means of birth control. Defendants also failed to disclose material facts regarding the safety and efficacy of YAZ/YASMIN, including information regarding increased adverse events, harmful side effects, and results of clinical studies showing that use of the medication could be life threatening.

91. Defendants had a duty to provide Plaintiff, physicians, and other consumers with true and accurate information and warnings of any known risks and side effects of the pharmaceuticals they marketed, distributed and sold.

92. Defendants knew or should have known, based on their prior experience, adverse event reports, studies and knowledge of the efficacy and safety failures with YAZ/YASMIN, that their representations regarding YAZ/YASMIN were false, and that they had a duty to disclose the dangers of YAZ/YASMIN.

93. Defendants made the representations and failed to disclose the material facts with the intent to induce consumers, including Plaintiff, to act in reliance by purchasing YAZ/YASMIN.

94. Plaintiff justifiably relied on Defendants' representations and nondisclosures by purchasing and using YAZ/YASMIN.

95. Defendants' misrepresentations and omissions regarding the safety and efficacy of YAZ/YASMIN was the direct and proximate cause of Plaintiff's injuries.

96. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants in an amount in excess of $150,000.00, plus delay damages, interest, costs and punitive damages.

COUNT VIII
BREACH OF EXPRESS WARRANTY

97. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

98. Defendants expressly warranted that YAZ/YASMIN was safe and effective to members of the consuming public, including Plaintiff.

99. Members of the consuming public, including consumers such as Plaintiff, were intended third party beneficiaries of the warranty.

100. Defendants marketed, promoted and sold YAZ/YASMIN as a safe method of birth control.

101. YAZ/YASMIN does not conform to these express representations because YAZ/YASMIN is not safe and has serious side effects, including death.

102. Defendants breached their express warranty in one or more of the following ways:

a. YAZ/YASMIN, as designed, manufactured, sold and/or supplied by the Defendants, was defectively designed and placed in to the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

b. Defendants failed to warn and/or place adequate warnings and instructions on YAZ/YASMIN;

c. Defendants failed to adequately test YAZ/YASMIN; and

d. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew the risk of injury from YAZ/YASMIN.

103. Plaintiff reasonably relied upon Defendants' warranty that YAZ/YASMIN was safe and effective when she purchased and used the medication.

104. Plaintiff's injuries were the direct and proximate result of Defendants' breach of their express warranty.

105. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including

Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants in an amount in excess of $150,000.00, plus delay damages, interest, and costs as allowed by law.

COUNT IX
FRAUD

106. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

107. Defendants widely advertised and promoted YAZ/YASMIN as a safe and effective medication.

108. Defendants had a duty to disclose material information about serious side effects to consumers such as Plaintiff.

109. Additionally, by virtue of Defendants' partial disclosures about the medication, in which Defendants' touted YAZ/YASMIN as a safe and effective medication, Defendants had a duty to disclose all facts about the risks associated with use of the medication, including the risks described in this complaint. Defendants intentionally failed to disclose this information for the purpose of inducing consumers, such as Plaintiff, to purchase Defendants' dangerous product.

110. Had Plaintiff been aware of the hazards associated with YAZ/YASMIN, Plaintiff would not have consumed the product that led proximately to Plaintiff's adverse health effects.

111. Defendants' advertisements regarding YAZ/YASMIN made material misrepresentations to the effect that YAZ/YASMIN was a safe and effective medication, which misrepresentations Defendants knew to be false, for the purpose of fraudulently inducing consumers, such as Plaintiff, to purchase such product. Plaintiff relied on these material misrepresentations when deciding to purchase and consume YAZ/YASMIN.

112. Upon information and belief, Plaintiff avers that Defendants actively and fraudulently concealed information in Defendants' exclusive possession regarding the hazards associated with YAZ/YASMIN with the purpose of preventing consumers, such as Plaintiff, from discovering these hazards.

WHEREFORE, Plaintiff demands judgment against Defendants in an amount in excess of $150,000.00, plus delay damages, interest, and costs as allowed by law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendants, jointly and severally, as follows:

A. For an award of compensatory damages, including damages against Defendants and each of them for wrongful death, medical and hospital expenses, loss of income, loss of consortium, and other damages according to proof at trial in excess of $75,000;

B. For an award of punitive or exemplary damages against Defendants and each of them in excess of $75,000;

C. For reasonable attorneys' fees and costs;

D. For pre-judgment interest; and

E. For such further and other relief the court deems just, equitable, and proper.

Dated: July 21, 2009

Respectfully Submitted,

_____

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Counsel for Plaintiff

JURY DEMAND

Plaintiff hereby demands a trial by jury on all triable issues.

_____

IN THE U.S. DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

GAIL BRINKER
15630 Zepernick Rd.
Pemberville, OH 43450

and

KENNETH BRINKER
15630 Zepernick Rd.
Pemberville, OH 43450

Plaintiffs,

v.

BAYER CORPORATION
c/o CSC-Lawyers Incorporating Service (Corporation Service Company)
50 W. Broad St. Suite 1800
Columbus, OH 43215

and

BAYER HEALTHCARE LLC,
c/o CSC-Lawyers Incorporating Service (Corporation Service Company)
50 W. Broad St. Suite 1800
Columbus, OH 43215

and

BAYER PHARMACEUTICALS CORPORATION,
c/o CSC-Lawyers Incorporating Service (Corporation Service Company)
50 W. Broad St. Suite 1800

CASE NO.

JUDGE

COMPLAINT WITH JURY DEMAND ENDORSED HEREON

David W. Zoll (0008548)
Michelle L. Kranz (0062479)
Pamela A. Borgess (0072789)
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Counsel for Plaintiffs

Columbus, OH 43215

and

BAYER HEALTHCARE PHARMACEUTICALS INC.
c/o CSC-Lawyers Incorporating Service (Corporation Service Company)
50 W. Broad St. Suite 1800
Columbus, OH 43215

and

BERLEX LABORATORIES, INC.
c/o CSC-Lawyers Incorporating Service (Corporation Service Company)
340 Changebridge Road
Montville, NJ 07045

and

BERLEX, INC.
c/o CSC-Lawyers Incorporating Service (Corporation Service Company)
340 Changebridge Road
Montville, NJ 07045

and

JOHN DOE MANUFACTURERS A-Z
[Real Names and Addresses Unknown]

and

JOHN DOE DISTRIBUTORS A-Z
[Real Names and Addresses Unknown]

Defendants.

Now come Gail and Kenneth Brinker, by and through the undersigned counsel, and for their Complaint hereby aver and state as follows:

NATURE OF THE ACTION

1. This is an action for strict product liability (Ohio R.C. § 2307.71 *et seq.*), fraudulent misrepresentation, civil conspiracy and commercial bribery, loss of consortium, and punitive damages brought by Plaintiff for damages associated with her ingestion of the pharmaceutical drug YAZ, an oral contraceptive developed, designed, licensed, manufactured, distributed, sold, and/or marketed by Defendants.

2. As a result of the ingestion of YAZ, Plaintiff Gail Brinker has suffered injuries to her person including, but not limited to, a pulmonary embolism.

THE PARTIES

3. Plaintiff Gail Brinker, (herein "Plaintiff"), resides in the village of Pemberville, Wood County, Ohio.

4. Plaintiff is married to Plaintiff Kenneth Brinker, who also resides in the village of Pemberville, Wood County, Ohio.

5. Defendant BAYER CORPORATION is, and at all times relevant was, a corporation organized under the laws of the State of Indiana with its headquarters and principal place of business at 100 Bayer Rd., Pittsburgh, Pennsylvania 15205.

6. At all times relevant, Defendant BAYER CORPORATION was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

7. Defendant BAYER HEALTHCARE LLC, is, and at times relevant was, a limited liability corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 100 Bayer Road, Pittsburg, PA 15205.

8. At all times relevant, Defendant BAYER HEALTHCARE LLC was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

9. Defendant BAYER HEALTHCARE LLC is wholly owned by Defendant BAYER CORPORATION.

10. Defendant BAYER PHARMACEUTICALS CORPORATION is, and at times relevant was, a corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 1400 Morgan Lane, West Haven, Connecticut.

11. At all times relevant, Defendant BAYER PHARMACEUTICALS CORPORATION was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

12. As of January 1, 2008, Defendant BAYER PHARMACEUTICALS CORPORATION was merged into Defendant BAYER HEALTHCARE PHARMACEUTICALS INC.

13. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC., is and at times relevant was, a corporation organized and existing under the laws of the State of Delaware, having a

principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

14. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc., and is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc.

15. At all times relevant, Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

16. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. applied for and received U.S. marketing approval of Yasmin and YAZ by the FDA, and is the holder of approved New Drug Application ("NDA") for Yasmin and YAZ.

17. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. are, and at all times relevant were, foreign corporations with their headquarters and principal places of business at Montville, New Jersey and with a post office address of P.O. Box 1000, Montville, New Jersey, 07045 and places of business located at 6 West Belt Road, Wayne, New Jersey 07470.

18. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. were integrated into Bayer HealthCare AG and operates as an integrated specialty pharmaceuticals business under the new name, Defendant Bayer Healthcare Pharmaceuticals, Inc.

19. At all times relevant, Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio,

either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

20. Defendants John Doe Manufacturers A-Z (fictitious-name designations of one or more individuals, partnerships, corporations, and/or other entities whose actual identities have yet to be determined) at all times relevant hereto were in the business of developing, researching, selling, distributing, designing, manufacturing, testing, evaluating, licensing, labeling, marketing, and/or placing, either directly or indirectly through third parties or related entities, pharmaceutical drugs including Yasmin and YAZ into interstate commerce, including in the Northern District of Ohio, and derived substantial revenue from these activities.

21. Defendants John Doe Distributors A-Z (fictitious-name designations of one or more individuals, partnerships, corporations, and/or other entities whose actual identities have yet to be determined) at all times relevant hereto were in the business of developing, researching, selling, distributing, designing, manufacturing, testing, evaluating, licensing, labeling, marketing, and/or placing, either directly or indirectly through third parties or related entities, pharmaceutical drugs including Yasmin and YAZ into interstate commerce, including in the Northern District of Ohio, and derived substantial revenue from these activities.

22. Defendants Bayer Corporation, Bayer Healthcare LLC, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Berlex Laboratories, Inc. and Berlex, Inc., and John Doe Manufacturers and Distributors A-Z shall be referred to herein individually by name or jointly as "Defendants."

23. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of

any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

24. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in interest, aider and abettor, co-conspirator and joint venturer of each of the remaining Defendants herein and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture.

JURISDICTION AND VENUE

25. This Court has jurisdiction over this action pursuant to 28 U.S.C.A. § 1332, as there is complete diversity of citizenship between Plaintiff and Defendants, and the amount in controversy exceeds $75,000, exclusive of interest and costs.

26. Venue is proper in the Northern District of Ohio pursuant to 28 U.S.C.A. § 1391, as a substantial part of the events giving rise to these claims occurred within this district, including the prescription and use of YAZ, as well as Plaintiff's resulting injuries.

27. The Court has personal jurisdiction over Defendants consistent with the Ohio and United States Constitution pursuant to Ohio R. C. § 2307.382(4) because Defendants caused tortious injury in Ohio by an act or omission outside Ohio by virtue of Defendants' regularly conducted business in Ohio from which they respectively derive substantial revenue. Defendants do substantial business in the State of Ohio and within the Northern District of Ohio, advertise in this district, and receive substantial compensation and profits from sales of Yasmin and YAZ within this District.

28. Defendants expected or should have expected that their business activities could or would have consequences within the State of Ohio, as well as throughout the United States.

FACTS

Yasmin and YAZ Background

29. Yasmin, (a predecessor to YAZ), known generically as drospirenone and ethinyl estradiol, is a combination birth control pill originally developed by Defendant BERLEX LABORATORIES, INC. and/or Defendant BERLEX, INC containing the hormones estrogen and progestin.

30. The estrogen is ethinyl estradiol and the progestin is drospirenone, (3 mg of drospirenone and 0.03 mg of ethinyl estradiol per tablet).

31. Combination birth control pills are referred to as combined hormonal oral contraceptives.

32. Yasmin was approved by the FDA in April, 2001.

33. In 2006, Bayer acquired Defendant BERLEX LABORATORIES, INC. and/or Defendant BERLEX, INC, and began marketing an almost identical drug, YAZ (which contains 3 mg of drospirenone and 0.02 mg of ethinyl estradiol per tablet).

34. The difference between YAZ/Yasmin and other birth control pills on the market is that drospirenone has never before been marketed in the United States and is unlike other progestins available in the United States.

35. Shortly after the introduction of combined oral contraceptives in the 1960s, doctors and researchers found that women using birth control pills had a higher risk of blood clots, heart attacks and strokes than women not using the pill. As a result, the various brands of birth control pills were reformulated to reduce the amounts of estrogen. As the amounts of estrogen levels reduced, so too did the risk of blood clots, heart attacks and strokes.

36. During this time, new progestins were being developed, which became known as "second generation" progestins (e.g. lovenorgestrel). These second generation progestins, when

combined with the lower amounts of the estrogen, ethinyl estradiol, helped to reduce the risk of blood clots, heart attacks and strokes and were considered safer for women.

37. During the 1990s, new "third generation" progestins were developed. Unfortunately, these "third generation" progestins (e.g. gestodene and desogestrel) have been associated with a greater risk of blood clots in the deep veins (deep vein thrombosis or "DVT") and lungs (pulmonary embolism or "PE"). As a result of this increased risk of blood clots, the FDA has required that products containing third generation progestins include a warning of the potentially increased risk of thrombosis.

38. Yasmin and YAZ contain the same estrogen component, ethinyl estradiol, that has been used in the lower dose birth control pills for decades.

39. However, drospirenone is a new type of progestin and is considered a "fourth generation" progestin. No other birth control pills contain drospirenone, except for a recently approved generic version of Yasmin and YAZ marketed under the trade name, Ocella.

40. Since drospirenone in birth control is new, there are not decades of data available to support its safe use as there are with second generation progestins. Studies that were done prior to FDA approval, however, indicate that drospirenone has certain effects that are different from those of traditional second generation progestins, and potentially more dangerous.

41. One possible mechanism of action is that drospirenone causes an increase in potassium levels in the blood, which can lead to a condition known as hyperkalemia if the potassium levels become too high.

42. Hyperkalemia can cause heart rhythm disturbances, such as extrasystolies, pauses or bradycardia. If left untreated, hyperkalemia can be fatal.

43. If hyperkalemia disrupts the normal heart rhythms, the flow of blood through the

heart can be slowed to the point that it permits blood clots to form. Blood clots in the heart can then lead to heart attacks, or the clots can break off and travel to the lungs where they can cause pulmonary embolism, or can travel to the brain causing stroke.

44. Another effect is a substantially increased risk of gallbladder complications.

45. During the brief time that Yasmin and YAZ have been sold in the United States, hundreds of reports of injury and death have been submitted to the FDA in association with Defendants' products.

46. In April 2002, the British Medical Journal reported that the Dutch College of General Practitioners recommended that older second generation birth control pills be prescribed in lieu of Yasmin as a result of 40 cases of venous thrombosis among women taking Yasmin.

47. In February 2003, a paper entitled *Thromboembolism Associated With the New Contraceptive Yasmin* was published in the British Medical Journal detailing a Netherlands Pharmacovigilance Centre report of five additional reports of thromboembolism where Yasmin was suspected as the cause, including two deaths.

48. In fact, in less than a five-year period, from the first quarter of 2004 through the third quarter of 2008, over 50 reports of death among users of Yasmin and YAZ have been filed with the FDA.

49. These reports include deaths associated with cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism and stroke in women in their child bearing years.

50. Some deaths reported occurred in women as young as 17 years old.

51. Significantly, reports of elevated potassium levels are frequently included among the symptoms of those suffering death while using Yasmin or YAZ.

Defendants' Over-Promotion, Fraud and Failures Regarding Yasmin and YAZ

52. Defendants market Yasmin and YAZ as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits.

53. However, because Yasmin and YAZ contain the fourth generation progestin drospirenone, they present additional health risks not associated with other birth control pills.

54. Defendants have been warned at least three times by the FDA; in 2003, 2008 and 2009, for misleading the public through the use of ads which overstate the efficacy of YAZ and/or its predecessor Yasmin, and minimize serious risks associated with the drug.

55. Indeed, the FDA felt Defendants' over-promotion of YAZ was so severe that it required Bayer to run new TV advertisements to correct the previous misleading YAZ advertisements.

56. Bayer ultimately agreed to spend at least $20 million on corrective TV advertisements and to submit all YAZ advertisements to the FDA for advanced screening for the next six years.

57. Defendants ignored the correlation between the use of Yasmin and YAZ and increased thrombosis formation despite the wealth of scientific information available.

58. Upon information and belief, Defendants knew or should have known about the correlation between the use of Yasmin and YAZ and a prothrombotic effect and still promoted, sold, advertised, and marketed the use of Yasmin and YAZ.

59. Defendants falsely and fraudulently represented to the medical and healthcare community, to Plaintiff, the FDA, and the public in general, that Yasmin and YAZ had been tested and was found to be safe and/or effective for its indicated use.

60. These false representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and

healthcare community in particular, to recommend, dispense and/or purchase Yasmin and YAZ for use as a contraceptive, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of Plaintiff.

61. Defendants knew and were aware or should have been aware that Yasmin and YAZ had not been sufficiently tested, was defective in its design and testing, and/or lacked adequate and/or sufficient warnings.

62. Defendants knew or should have known that Yasmin and YAZ had a potential to, could, and would cause severe and grievous injury and death to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate and/or down-played warnings.

63. In representations to Plaintiff, her healthcare providers, and/or the FDA, Defendants also fraudulently concealed and intentionally omitted the following material information:

a. That Yasmin/YAZ is not as safe as other available contraceptives;

b. That the risks of adverse events with Yasmin/YAZ (drospirenone and ethinyl estradiol) was higher than those of other available contraceptives;

c. That the risks of adverse events with Yasmin/YAZ was not adequately tested and/or known by Defendants;

d. Plaintiff was put at risk of experiencing serious and dangerous side effects including, but not limited to, a pulmonary embolism, as well as other severe and personal injuries, physical pain, and mental anguish;

e. That patients needed to be monitored more regularly than normal while using Yasmin/YAZ; and/or

f. That Yasmin/YAZ was designed, tested, manufactured, marketed, produced, distributed and advertised negligently, defectively, fraudulently and improperly.

64. Defendants were under a duty to disclose to Plaintiff and her physicians, hospitals, healthcare providers and/or the FDA the defective nature of Yasmin and YAZ.

65. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to person who used Yasmin and YAZ, including Plaintiff.

66. Defendants made the misrepresentations and/or actively concealed information concerning the safety and efficacy of Yasmin and YAZ with the intention and specific desire that the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, would rely on such in selecting Yasmin and YAZ as a contraceptive.

67. Defendants made these misrepresentations and/or actively concealed information concerning the safety and efficacy of Yasmin and YAZ in their labeling, advertising, product inserts, promotional material or other marketing efforts.

68. The misrepresentations of and/or active concealment by Defendants were perpetuated directly and/or indirectly by Defendants, its sales representative, employees, distributors, agents and/or detail persons.

69. Defendants knew that Plaintiff, her healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Yasmin and YAZ, as set forth herein.

70. The misrepresentations of and/or active concealment by Defendants constitute a continuing tort. Indeed, through Defendants' product inserts, Defendants continue to misrepresent the potential risks and serious side effects associated with the use of Yasmin and YAZ.

71. Moreover, Defendants had a post-sale duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, about the potential risks and serious side effects associated with the use of YAZ in a timely manner, yet

they failed to provide such warning.

FACTS REGARDING PLAINTIFF GAIL BRINKER

72. Plaintiff was prescribed YAZ by her health care provider.

73. Plaintiff justifiably relied on and/or was induced by the misrepresentations and/or active concealment of Defendants to purchase and ingest YAZ to her detriment.

74. As a result of using Defendants' product YAZ, in March of 2008, Plaintiff suffered serious and life-threatening side effects including but not limited to, a pulmonary embolism, as well as other severe and personal injuries, including future thromboembolic events, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses, the need for lifelong medical treatment, monitoring and/or medications, and the fear of developing any of the above named health consequences.

75. Plaintiff did not discover, nor did she have any reason to discover that her injury was a result of a defective drug and/or the wrongful conduct of Defendants, as set forth herein, until at least April of 2009.

CAUSES OF ACTION

COUNTS I-IV

Defective Manufacturing/Construction (R.C. § 2307.74)

Defective Design/Formulation (R.C. § 2307.75)

Defective Warning/Instruction (R.C. § 2307.76)

Defective Due to Nonconformity with Representation (R.C. § 2307.77)

76. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

77. At all times relevant to this action, Defendants were the manufacturers, as defined at Revised Code § 2307.71, and distributors, which designed, produced, created, made, constructed and/or assembled the drugs, Yasmin and YAZ, that were placed into the stream of commerce.

78. The Yasmin and YAZ birth control pills were expected to and did reach the ultimate users, including Plaintiff, without substantial change in the condition they were sold.

79. The Yasmin and YAZ birth control pills manufactured, designed, sold, distributed, supplied, promoted and/or place in the stream of commerce by Defendant were defective in their:

a. Manufacture and construction pursuant to the provisions of Ohio Revised Code § 2307.74;

b. Design pursuant to the provisions of Ohio Revised Code § 2307.75;

c. Inadequate warning or instruction pursuant to the provisions of Ohio Revised Code § 2307.76, and/or

d. Failure to conform, when it left the control of Defendants, to their representations, pursuant to the provisions of Ohio Revised Code § 2307.77.

80. Specifically, Defendants' failures, which permitted defective drugs, Yasmin and YAZ, to be placed in the stream of commerce, include, but are not necessarily limited to:

a. Defendants' failure to exercise reasonable care in the manufacture, design and testing of Yasmin and YAZ;

b. Defendants' failure to include adequate warnings that would alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, of the substantially increased risks and serious side effects of the drug;

c. Defendants' failure to adequately and properly test and inspect the drug before placing the drug on the market;

d. Defendants' failure to conduct sufficient testing and inspection of the drug which, if properly performed, would have shown that the drug had serious increased side effects, including, but not limited to, a pulmonary embolism, and other serious and life threatening side effects;

e. Defendants' failure to adequately warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff of the potential risks and other serious side effects associated with the drug, including, among other things, a pulmonary embolism and other serious and life threatening side effects;

f. Defendants' failure to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risks associated with the use of the drug;

g. Defendants' failure to recall and/or remove the drug from the stream of commerce despite the fact that Defendants knew or should have known of the defective and unreasonably dangerous nature of the drug, including the significant health risks associated with the use of the drug; and

h. Defendants' encouragement of misuse and overuse while failing to disclose the side effects of the drug to the medical, pharmaceutical and/or scientific communities, and users and/or consumers, including Plaintiff, in order to maximize profit from sales.

81. Yasmin and YAZ were unsafe for normal or reasonably anticipated use.

82. Plaintiff was using the drug in the manner for which it was intended and/or in a reasonably foreseeable manner.

83. Plaintiff could not, through the exercise of reasonable care, have discovered the defects or perceived the dangers posed by the drug.

84. As a direct and proximate result of this defective product, Plaintiff has been injured and incurred substantial damages, including, but not limited to, a pulmonary embolism, as well as other severe and personal injuries, including future thromboembolic events, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses, the need for lifelong medical treatment, monitoring and/or medications, and the fear of developing any of the above named health consequences.

85. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to recover punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

COUNT V
Fraudulent Misrepresentation

86. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows.

87. Defendants, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and promotion of Yasmin and YAZ, owed a duty not to deceive the Plaintiff, her health care providers and the public regarding the character, safety, quality and/or effectiveness of their drug.

88. The duty not to deceive is distinct from than the duty to warn and thus, was not abrogated by the Ohio Product Liability Act found at Ohio R.C. § 2307.71 *et seq.*

89. Since the drug's approval in April of 2001, and on multiple occasions to the present date, Defendants fraudulently misrepresented and published information in various forms of media (including, but not limited to, ad campaigns, television, internet, etc.) regarding their product's character, safety, quality and/or effectiveness, including, but not limited to, the public ad campaigns which were the subject of the FDA's 2003, 2008 and 2009 warnings.

90. At the time of Defendants' fraudulent misrepresentations, Plaintiff was unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

91. Defendants breached their duties to Plaintiff by providing false, incomplete and misleading information regarding Yasmin and YAZ.

92. Defendants acted with deliberate intent to deceive and mislead Plaintiff, her medical providers, and the public.

93. Plaintiff reasonably relied upon Defendants' deceptive, inaccurate and fraudulent misrepresentations.

94. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff suffered serious and life-threatening side effects including but not limited to, a pulmonary embolism, as well as other severe and personal injuries, including future thromboembolic events, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses, the need for lifelong medical treatment, monitoring and/or medications, and the fear of developing any of the above named health consequences.

95. Defendants' conduct was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety to patients/consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

COUNTS VI-VII
Civil Conspiracy and Commercial Bribery

96. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

97. Defendants committed civil conspiracy, commercial bribery and conspiracy to commit commercial bribery in that fiduciaries of Defendants knowingly and/or intentionally offered, conferred, or agreed to confer benefits, gifts, and/or gratuities or conspired to do the same upon physicians, pharmacists, and insurance companies for the purpose of enticing these

entities to use the drugs Yasmin and YAZ, and to convince their patients and others of the safety and effectiveness of Yasmin and YAZ.

COUNT VIII
Loss of Consortium

98. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

99. As a result of the foregoing acts and omissions, and the resulting injuries, including but not limited to, personal injuries, medical expenses, and pain and suffering sustained by Plaintiff. Plaintiff Kenneth Brinker has suffered the loss of companionship, society, services, and consortium of his wife.

COUNT IX
Punitive Damages

100.Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

101.Defendants engaged in fraudulent and malicious conduct towards the Plaintiff, her medical providers and the public, and thereby acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiff and the public.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendants, jointly and severally, as follows:

A. For an award of compensatory damages, including damages against Defendants and each of them for wrongful death, medical and hospital expenses, loss of income, loss of consortium, and other damages according to proof at trial in excess of $75,000;

B. For an award of punitive or exemplary damages against Defendants and each of them in excess of $75,000;

C. For reasonable attorneys' fees and costs;

D. For pre-judgment interest; and

E. For such further and other relief the court deems just, equitable, and proper.

Dated: July 21, 2009

Respectfully Submitted,

/s/David W. Zoll
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/s/Michelle Kranz
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/s/Pamela A. Borgess
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Email: pamela@toledolaw.com

Counsel for Plaintiffs

JURY DEMAND

Plaintiff hereby demands a trial by jury on all triable issues.

/s/David W. Zoll
David W. Zoll (0008548)

IN THE U.S. DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

LAUREN CATHIS
2829 Prairie College St. SW
Canton, OH 44706

Plaintiff,

v.

BAYER CORPORATION
c/o CSC-Lawyers Incorporating Service (Corporation Service Company)
50 W. Broad St. Suite 1800
Columbus, OH 43215

and

BAYER HEALTHCARE LLC,
c/o CSC-Lawyers Incorporating Service (Corporation Service Company)
50 W. Broad St. Suite 1800
Columbus, OH 43215

and

BAYER PHARMACEUTICALS CORPORATION,
c/o CSC-Lawyers Incorporating Service (Corporation Service Company)
50 W. Broad St. Suite 1800
Columbus, OH 43215

and

BAYER HEALTHCARE

CASE NO.

JUDGE

COMPLAINT WITH JURY DEMAND ENDORSED HEREON

David W. Zoll (0008548)
Michelle L. Kranz (0062479)
Pamela A. Borgess (0072789)
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Counsel for Plaintiff

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and

BERLEX LABORATORIES, INC.
c/o CSC-Lawyers Incorporating Service (Corporation Service Company)
340 Changebridge Road
Montville, NJ 07045

and

BERLEX, INC.
c/o CSC-Lawyers Incorporating Service (Corporation Service Company)
340 Changebridge Road
Montville, NJ 07045

and

JOHN DOE MANUFACTURERS A-Z
[Real Names and Addresses Unknown]

and

JOHN DOE DISTRIBUTORS A-Z
[Real Names and Addresses Unknown]

Defendants.

Now comes Plaintiff, by and through the undersigned counsel, and for her Complaint hereby avers and states as follows:

NATURE OF THE ACTION

1. This is an action for strict product liability (Ohio R.C. § 2307.71 *et seq.*), fraudulent misrepresentation, civil conspiracy and commercial bribery, loss of consortium, and punitive damages brought by Plaintiff for damages associated with her ingestion of the pharmaceutical drug Yasmin, an oral contraceptive developed, designed, licensed, manufactured, distributed, sold, and/or marketed by Defendants.

2. As a result of the ingestion of Yasmin, Plaintiff suffered injuries to her person including, but not limited to, the removal of her gallbladder in December of 2007.

THE PARTIES

3. Plaintiff Lauren Cathis, (herein "Plaintiff"), resides in the city of Canton, Stark County, Ohio.

4. Defendant BAYER CORPORATION is, and at all times relevant was, a corporation organized under the laws of the State of Indiana with its headquarters and principal place of business at 100 Bayer Rd., Pittsburgh, Pennsylvania 15205.

5. At all times relevant, Defendant BAYER CORPORATION was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

6. Defendant BAYER HEALTHCARE LLC, is, and at times relevant was, a limited liability corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 100 Bayer Road, Pittsburg, PA 15205.

7. At all times relevant, Defendant BAYER HEALTHCARE LLC was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or

indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

8. Defendant BAYER HEALTHCARE LLC is wholly owned by Defendant BAYER CORPORATION.

9. Defendant BAYER PHARMACEUTICALS CORPORATION is, and at times relevant was, a corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 1400 Morgan Lane, West Haven, Connecticut.

10. At all times relevant, Defendant BAYER PHARMACEUTICALS CORPORATION was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

11. As of January 1, 2008, Defendant BAYER PHARMACEUTICALS CORPORATION was merged into Defendant BAYER HEALTHCARE PHARMACEUTICALS INC.

12. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC., is and at times relevant was, a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

13. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc., and is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc.

14. At all times relevant, Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling,

marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

15. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. applied for and received U.S. marketing approval of Yasmin and YAZ by the FDA, and is the holder of approved New Drug Application ("NDA") for Yasmin and YAZ.

16. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. are, and at all times relevant were, foreign corporations with their headquarters and principal places of business at Montville, New Jersey and with a post office address of P.O. Box 1000, Montville, New Jersey, 07045 and places of business located at 6 West Belt Road, Wayne, New Jersey 07470.

17. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. were integrated into Bayer HealthCare AG and operates as an integrated specialty pharmaceuticals business under the new name, Defendant Bayer Healthcare Pharmaceuticals, Inc.

18. At all times relevant, Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

19. Defendants John Doe Manufacturers A-Z (fictitious-name designations of one or more individuals, partnerships, corporations, and/or other entities whose actual identities have yet to be determined) at all times relevant hereto were in the business of developing, researching, selling, distributing, designing, manufacturing, testing, evaluating, licensing, labeling, marketing, and/or placing, either directly or indirectly through third parties or related entities,

pharmaceutical drugs including Yasmin and YAZ into interstate commerce, including in the Northern District of Ohio, and derived substantial revenue from these activities.

20. Defendants John Doe Distributors A-Z (fictitious-name designations of one or more individuals, partnerships, corporations, and/or other entities whose actual identities have yet to be determined) at all times relevant hereto were in the business of developing, researching, selling, distributing, designing, manufacturing, testing, evaluating, licensing, labeling, marketing, and/or placing, either directly or indirectly through third parties or related entities, pharmaceutical drugs including Yasmin and YAZ into interstate commerce, including in the Northern District of Ohio, and derived substantial revenue from these activities.

21. Defendants Bayer Corporation, Bayer Healthcare LLC, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Berlex Laboratories, Inc. and Berlex, Inc., and John Doe Manufacturers and Distributors A-Z shall be referred to herein individually by name or jointly as "Defendants."

22. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

23. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in interest, aider and abettor, co-conspirator and joint venturer of each of the remaining Defendants herein and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture.

JURISDICTION AND VENUE

24. This Court has jurisdiction over this action pursuant to 28 U.S.C.A. § 1332, as there is complete diversity of citizenship between Plaintiff and Defendants, and the amount in controversy exceeds $75,000, exclusive of interest and costs.

25. Venue is proper in the Northern District of Ohio pursuant to 28 U.S.C.A. § 1391, as a substantial part of the events giving rise to these claims occurred within this district, including the prescription and use of YAZ, as well as Plaintiff's resulting injuries.

26. The Court has personal jurisdiction over Defendants consistent with the Ohio and United States Constitution pursuant to Ohio R. C. § 2307.382(4) because Defendants caused tortious injury in Ohio by an act or omission outside Ohio by virtue of Defendants' regularly conducted business in Ohio from which they respectively derive substantial revenue. Defendants do substantial business in the State of Ohio and within the Northern District of Ohio, advertise in this district, and receive substantial compensation and profits from sales of Yasmin and YAZ within this District.

27. Defendants expected or should have expected that their business activities could or would have consequences within the State of Ohio, as well as throughout the United States.

FACTS

Yasmin and YAZ Background

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35. During this time, new progestins were being developed, which became known as "second generation" progestins (e.g. lovenorgestrel). These second generation progestins, when combined with the lower amounts of the estrogen, ethinyl estradiol, helped to reduce the risk of blood clots, heart attacks and strokes and were considered safer for women.

36. During the 1990s, new "third generation" progestins were developed. Unfortunately, these "third generation" progestins (e.g. gestodene and desogestrel) have been associated with a greater risk of blood clots in the deep veins (deep vein thrombosis or "DVT") and lungs (pulmonary embolism or "PE"). As a result of this increased risk of blood clots, the FDA has

required that products containing third generation progestins include a warning of the potentially increased risk of thrombosis.

37. Yasmin and YAZ contain the same estrogen component, ethinyl estradiol, that has been used in the lower dose birth control pills for decades.

38. However, drospirenone is a new type of progestin and is considered a "fourth generation" progestin. No other birth control pills contain drospirenone, except for a recently approved generic version of Yasmin and YAZ marketed under the trade name, Ocella.

39. Since drospirenone in birth control is new, there are not decades of data available to support its safe use as there are with second generation progestins. Studies that were done prior to FDA approval, however, indicate that drospirenone has certain effects that are different from those of traditional second generation progestins, and potentially more dangerous.

40. One possible mechanism of action is that drospirenone causes an increase in potassium levels in the blood, which can lead to a condition known as hyperkalemia if the potassium levels become too high.

41. Hyperkalemia can cause heart rhythm disturbances, such as extrasystolies, pauses or bradycardia. If left untreated, hyperkalemia can be fatal.

42. If hyperkalemia disrupts the normal heart rhythms, the flow of blood through the heart can be slowed to the point that it permits blood clots to form, including deep vein thrombosis. Blood clots in the heart can then lead to heart attacks, or the clots can break off and travel to the lungs where they can cause pulmonary embolism, or can travel to the brain causing stroke.

43. Another effect is a substantially increased risk of gallbladder complications.

44. During the brief time that Yasmin and YAZ have been sold in the United States,

hundreds of reports of injury and death have been submitted to the FDA in association with Defendants' products.

Defendants' Over-Promotion, Fraud and Failures Regarding Yasmin and YAZ

45. Defendants market Yasmin and YAZ as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits.

46. However, because Yasmin and YAZ contain the fourth generation progestin drospirenone, they present additional health risks not associated with other birth control pills.

47. Defendants have been warned at least three times by the FDA; in 2003, 2008 and 2009, for misleading the public through the use of ads which overstate the efficacy of YAZ and/or its predecessor Yasmin, and minimize serious risks associated with the drug.

48. Indeed, the FDA felt Defendants' over-promotion of YAZ was so severe that it required Bayer to run new TV advertisements to correct the previous misleading YAZ advertisements.

49. Bayer ultimately agreed to spend at least $20 million on corrective TV advertisements and to submit all YAZ advertisements to the FDA for advanced screening for the next six years.

50. Defendants ignored the correlation between the use of Yasmin and YAZ and increased thrombosis formation despite the wealth of scientific information available.

51. Upon information and belief, Defendants knew or should have known about the correlation between the use of Yasmin and YAZ and gallbladder complications and still promoted, sold, advertised, and marketed the use of Yasmin and YAZ.

52. Defendants falsely and fraudulently represented to the medical and healthcare community, to Plaintiff, the FDA, and the public in general, that Yasmin and YAZ had been tested and was found to be safe and/or effective for its indicated use.

53. These false representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, dispense and/or purchase Yasmin and YAZ for use as a contraceptive, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of Plaintiff.

54. Defendants knew and were aware or should have been aware that Yasmin and YAZ had not been sufficiently tested, was defective in its design and testing, and/or lacked adequate and/or sufficient warnings.

55. Defendants knew or should have known that Yasmin and YAZ had a potential to, could, and would cause severe and grievous injury and death to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate and/or down-played warnings.

56. In representations to Plaintiff, her healthcare providers, and/or the FDA, Defendants also fraudulently concealed and intentionally omitted the following material information:

a. That Yasmin/YAZ is not as safe as other available contraceptives;

b. That the risks of adverse events with Yasmin/YAZ (drospirenone and ethinyl estradiol) was higher than those of other available contraceptives;

c. That the risks of adverse events with Yasmin/YAZ was not adequately tested and/or known by Defendants;

d. Plaintiff was put at risk of experiencing serious and dangerous side effects including, but not limited to, gallbladder complications, as well as other severe and personal injuries, physical pain, and mental anguish;

e. That patients needed to be monitored more regularly than normal while using Yasmin/YAZ; and/or

f. That Yasmin/YAZ was designed, tested, manufactured, marketed, produced,

distributed and advertised negligently, defectively, fraudulently and improperly.

57. Defendants were under a duty to disclose to Plaintiff and her physicians, hospitals, healthcare providers and/or the FDA the defective nature of Yasmin and YAZ.

58. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to person who used Yasmin and YAZ, including Plaintiff.

59. Defendants made the misrepresentations and/or actively concealed information concerning the safety and efficacy of Yasmin and YAZ with the intention and specific desire that the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, would rely on such in selecting Yasmin and YAZ as a contraceptive.

60. Defendants made these misrepresentations and/or actively concealed information concerning the safety and efficacy of Yasmin and YAZ in their labeling, advertising, product inserts, promotional material or other marketing efforts.

61. The misrepresentations of and/or active concealment by Defendants were perpetuated directly and/or indirectly by Defendants, its sales representative, employees, distributors, agents and/or detail persons.

62. Defendants knew that Plaintiff, her healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Yasmin and YAZ, as set forth herein.

63. The misrepresentations of and/or active concealment by Defendants constitute a continuing tort. Indeed, through Defendants' product inserts, Defendants continue to misrepresent the potential risks and serious side effects associated with the use of Yasmin and YAZ.

64. Moreover, Defendants had a post-sale duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, about the potential risks and serious side effects associated with the use of YAZ in a timely manner, yet they failed to provide such warning.

FACTS REGARDING PLAINTIFF LAUREN CATHIS

65. Plaintiff Lauren Cathis was prescribed Yasmin by her health care provider.

66. Plaintiff justifiably relied on and/or was induced by the misrepresentations and/or active concealment of Defendants to purchase and ingest Yasmin to her detriment.

67. As a result of using Defendants' product Yasmin, Plaintiff sustained serious side effects including, but not limited to, removal of her gallbladder in December of 2007, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses, medical monitoring and/or medications, and the fear of developing additional health consequences.

68. Plaintiff did not discover, nor did she have any reason to discover that her injury was a result of a defective drug and/or the wrongful conduct of Defendants, as set forth herein, until at least July of 2009.

CAUSES OF ACTION

COUNTS I-IV

Defective Manufacturing/Construction (R.C. § 2307.74)

Defective Design/Formulation (R.C. § 2307.75)

Defective Warning/Instruction (R.C. § 2307.76)

Defective Due to Nonconformity with Representation (R.C. § 2307.77)

69. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

70. At all times relevant to this action, Defendants were the manufacturers, as defined at Revised Code § 2307.71, and distributors, which designed, produced, created, made, constructed and/or assembled the drugs, Yasmin and YAZ, that were placed into the stream of commerce.

71. The Yasmin and YAZ birth control pills were expected to and did reach the ultimate users, including Plaintiff, without substantial change in the condition they were sold.

72. The Yasmin and YAZ birth control pills manufactured, designed, sold, distributed, supplied, promoted and/or place in the stream of commerce by Defendant were defective in their:

a. Manufacture and construction pursuant to the provisions of Ohio Revised Code § 2307.74;

b. Design pursuant to the provisions of Ohio Revised Code § 2307.75;

c. Inadequate warning or instruction pursuant to the provisions of Ohio Revised Code § 2307.76, and/or

d. Failure to conform, when it left the control of Defendants, to their representations, pursuant to the provisions of Ohio Revised Code § 2307.77.

73. Specifically, Defendants' failures, which permitted defective drugs, Yasmin and YAZ, to be placed in the stream of commerce, include, but are not necessarily limited to:

a. Defendants' failure to exercise reasonable care in the manufacture, design and testing of Yasmin and YAZ;

b. Defendants' failure to include adequate warnings that would alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, of the substantially increased risks and serious side effects of the drug;

c. Defendants' failure to adequately and properly test and inspect the drug before placing the drug on the market;

d. Defendants' failure to conduct sufficient testing and inspection of the drug which, if properly performed, would have shown that the drug had serious increased side effects, including, but not limited to, gallbladder complications, and other serious and life threatening side effects;

e. Defendants' failure to adequately warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff of the potential risks and other serious side effects associated with the drug, including, among other things, gallbladder complications and other serious and life threatening side effects;

f. Defendants' failure to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risks associated with the use of the drug;

g. Defendants' failure to recall and/or remove the drug from the stream of commerce despite the fact that Defendants knew or should have known of the defective and unreasonably dangerous nature of the drug, including the significant health risks associated with the use of the drug; and

h. Defendants' encouragement of misuse and overuse while failing to disclose the side effects of the drug to the medical, pharmaceutical and/or scientific communities, and users and/or consumers, including Plaintiff, in order to maximize profit from sales.

74. Yasmin and YAZ were unsafe for normal or reasonably anticipated use.

75. Plaintiff was using the drug in the manner for which it was intended and/or in a reasonably foreseeable manner.

76. Plaintiff could not, through the exercise of reasonable care, have discovered the defects or perceived the dangers posed by the drug.

77. As a direct and proximate result of this defective product, Plaintiff sustained serious side effects including, but not limited to, removal of her gallbladder, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses, medical monitoring and/or medications, and the fear of developing additional health consequences.

78. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to recover punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

COUNT V
Fraudulent Misrepresentation

79. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows.

80. Defendants, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and promotion of Yasmin and YAZ, owed a duty not to deceive the Plaintiff, her health care providers and the public regarding the character, safety, quality and/or effectiveness of their drug.

81. The duty not to deceive is distinct from than the duty to warn and thus, was not abrogated by the Ohio Product Liability Act found at Ohio R.C. § 2307.71 *et seq.*

82. Since the drug's approval in April of 2001, and on multiple occasions to the present date, Defendants fraudulently misrepresented and published information in various forms of media (including, but not limited to, ad campaigns, television, internet, etc.) regarding their product's character, safety, quality and/or effectiveness, including, but not limited to, the public ad campaigns which were the subject of the FDA's 2003, 2008 and 2009 warnings.

83. At the time of Defendants' fraudulent misrepresentations, Plaintiff was unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

84. Defendants breached their duties to Plaintiff by providing false, incomplete and misleading information regarding Yasmin and YAZ.

85. Defendants acted with deliberate intent to deceive and mislead Plaintiff, her medical providers, and the public.

86. Plaintiff reasonably relied upon Defendants' deceptive, inaccurate and fraudulent misrepresentations.

87. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff sustained serious side effects including, but not limited to, removal of her gallbladder, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses, medical monitoring and/or medications, and the fear of developing additional health consequences.

88. Defendants' conduct was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety to patients/consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

COUNTS VI-VII
Civil Conspiracy and Commercial Bribery

89. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

90. Defendants committed civil conspiracy, commercial bribery and conspiracy to commit commercial bribery in that fiduciaries of Defendants knowingly and/or intentionally offered, conferred, or agreed to confer benefits, gifts, and/or gratuities or conspired to do the same upon physicians, pharmacists, and insurance companies for the purpose of enticing these entities to use the drugs Yasmin and YAZ, and to convince their patients and others of the safety and effectiveness of Yasmin and YAZ.

COUNT VIII
Punitive Damages

102. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

103. Defendants engaged in fraudulent and malicious conduct towards the Plaintiff, her medical providers and the public, and thereby acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiff and the public.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendants, jointly and severally, as follows:

A. For an award of compensatory damages, including damages against Defendants and each of them for wrongful death, medical and hospital expenses, loss of income, loss of consortium, and other damages according to proof at trial in excess of $75,000;

B. For an award of punitive or exemplary damages against Defendants and each of them in excess of $75,000;

C. For reasonable attorneys' fees and costs;

D. For pre-judgment interest; and

E. For such further and other relief the court deems just, equitable, and proper.

Dated: July 21, 2009

Respectfully Submitted,

/s/David W. Zoll
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Counsel for Plaintiff

JURY DEMAND

Plaintiff hereby demands a trial by jury on all triable issues.

/s/David W. Zoll
David W. Zoll (0008548)

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

ANNE MARIE EAKINS, and
JONATHAN EAKINS
1059 Glendalough
Grafton, OH 44044

Plaintiffs,

v.

BAYER CORPORATION,
an Indiana corporation
c/o CSC-Lawyers Incorporating
Service (Corporation Service Company)
50 W. Broad St. Suite 1800
Columbus, OH 43215

BAYER HEALTHCARE
PHARMACEUTICALS INC.,
a Delaware corporation
c/o CSC-Lawyers Incorporating
Service (Corporation Service Company)
50 W. Broad St. Suite 1800
Columbus, OH 43215

BAYER HEALTHCARE, LLC,
a Delaware corporation
c/o CSC-Lawyers Incorporating
Service (Corporation Service Company)
50 W. Broad St. Suite 1800
Columbus, OH 43215

BERLEX LABORATORIES
INTERNATIONAL, INC.,
a Delaware corporation
c/o CSC-Lawyers Incorporating
Service (Corporation Service Company)
50 W. Broad St. Suite 1800
Columbus, OH 43215

Defendants.

Civil Action No. _____

COMPLAINT AND
JURY DEMAND

Plaintiffs, by and through counsel, and for their Complaint against Defendants, allege as follows:

PARTIES AND JURISDICTION

1. Plaintiff Anne Marie Eakins is a resident and citizen of Grafton, OH, located in Lorain County.

2. Plaintiff Jonathan Eakins is the husband of Anne Marie Eakins and also a resident and citizen of Grafton, OH, located in Lorain County.

3. Plaintiff Anne Marie Eakins was prescribed and ingested Yaz, and while using Yaz suffered multiple bilateral pulmonary emboli on November 29, 2007.

4. Plaintiff alleges an amount in controversy in excess of Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs.

5. Defendant Bayer Corporation is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. Defendant Bayer Corporation is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz. At all relevant times, Defendant Bayer Corporation conducted regular and sustained business in Ohio by selling and distributing its products in Ohio and engaged in substantial commerce and business activity in Lorain County.

6. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a Delaware corporation, with its principal place of business at 6 West Belt Road, Wayne, New Jersey 07470. Bayer Healthcare Pharmaceuticals, Inc. was created by the integration

of Bayer Healthcare and Berlex Laboratories. Defendant Bayer Healthcare Pharmaceuticals, Inc. is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz. At all relevant times, Defendant Bayer Healthcare Pharmaceuticals, Inc. conducted regular and sustained business in Ohio by selling and distributing its products in Ohio and engaged in substantial commerce and business activity in Lorain County.

7. Defendant Bayer Healthcare, LLC is a Delaware limited liability company, with its principal place of business at 555 White Plains Road, Tarrytown, New York 10591. Bayer Healthcare, LLC was involved in the integration of Bayer Healthcare and Berlex Laboratories. Defendant Bayer Healthcare, LLC is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz. At all relevant times, Defendant Bayer Healthcare, LLC conducted regular and sustained business in Ohio by selling and distributing its products in Ohio and engaged in substantial commerce and business activity in Lorain County.

8. Defendant Berlex Laboratories International, Inc. was a Delaware corporation with its principal place of business in Montville, New Jersey. Berlex Laboratories International, Inc. was integrated with Bayer Healthcare, leading to the creation of Bayer Healthcare Pharmaceuticals, Inc. Defendant Berlex Laboratories International, Inc. was engaged in the business of researching, developing, designing,

licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz. At all relevant times, Defendant Berlex Laboratories International, Inc. conducted regular and sustained business in Ohio by selling and distributing its products in Ohio and engaged in substantial commerce and business activity in Lorain County.

9. Defendants Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, and Berlex Laboratories International, Inc. are collectively referred to herein as "Bayer" or "Defendants."

10. This court has jurisdiction over this action pursuant to 28 U.S.C. §1332 because there is complete diversity of citizenship between the parties, and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

11. Venue in this district is appropriate under 28 U.S.C. §1391 because a substantial part of the events giving rise to this claim occurred in the district as Plaintiff Anne Marie Eakins was prescribed and used Yaz in this district, and because she resided in this district at the time of her injuries.

FACTUAL BACKGROUND

Nature of the Case

12. Plaintiffs brings this case against Defendants for damages associated with Plaintiff Anne Marie Eakin's ingestion of the pharmaceutical drug Yaz (ethinyl estradiol and drospirenone), an oral contraceptive designed, manufactured, marketed, and distributed by Defendants. Specifically, Plaintiff suffered multiple bilateral pulmonary

emboli on November 29, 2007 as a direct result of her use of Yaz. Her husband, Jonathan Eakins has suffered a loss of consortium.

Bayer's Combined Oral Contraceptives – Yasmin and Yaz

13. Yasmin and Yaz are birth control pills manufactured and marketed by Bayer. They are combination oral contraceptives, or "COCs," meaning that they contain an estrogen component and a progestin component. Together, these steroidal components work together in COCs to suppress ovulation, fertilization, and implantation and thus prevent pregnancy.

14. Yasmin and Yaz were approved by the Food and Drug Administration for marketing in 2001 and 2006 respectively.

Yasmin and Yaz Contain a "Fourth Generation" Progestin

15. The estrogen component in Yasmin and Yaz is known generically as ethinyl estradiol. The progestin component is known as drospirenone. Yasmin contains 0.03 milligrams of ethinyl estradiol, and Yaz contains 0.02 milligrams of ethinyl estradiol. Both products contain 3 milligrams of drospirenone.

16. Yasmin and Yaz are different from other combined hormonal birth control pills in that they contain drospirenone, a progestin that is unlike other progestins available in the United States and was never before marketed in the United States prior to its use in Yasmin.

17. Shortly after the introduction of combined oral contraceptives in the 1960's, doctors and researchers found that women using birth control pills had a higher risk of blood clots, heart attacks, and strokes than women not using the pill. As a result, the various brands of birth control pills were reformulated to reduce the amounts of

estrogen. As the amounts of estrogen levels reduced, so too did the risk of blood clots, heart attacks, and strokes.

18. During this time, new progestins were being developed, which became known as "second generation" progestins (e.g. lovenorgestrel). These second generation progestins, when combined with the lower amounts of the estrogen, ethinyl estradiol, helped to reduce the risk of blood clots, heart attacks, and strokes and were considered safer for women.

19. During the 1990's, new "third generation" progestins were developed. Unfortunately, these "third generation" progestins (e.g. gestodene and desogestrel) have been associated with a greater risk of blood clots in the deep veins (deep vein thrombosis or "DVT") and lungs (pulmonary embolism or "PE"). As a result of this increased risk of blood clots, the FDA has required that products containing third generation progestins include a Warning of the potentially increased risk of thrombosis.

20. Yasmin and Yaz contain the same estrogen component, ethinyl estradiol, that has been used in the lower dose birth control pills for decades.

21. However, drospirenone is a new type of progestin and is considered a "fourth generation" progestin. No other birth control pills contain drospirenone, except for a recently approved generic version of Yasmin and Yaz marketed under the trade name Ocella.

22. Since drospirenone is new, there are not decades of data available to support its safe use as there are with second generation progestins. Studies that were done prior to FDA approval, however, indicate that drospirenone has certain effects that

are different from those of traditional second generation progestins, and potentially more dangerous.

23. One possible mechanism of action is that drospirenone causes an increase in potassium levels in the blood, which can lead to a condition known as hyperkalemia if the potassium levels become too high.

24. Hyperkalemia can cause heart rhythm disturbances, such as extrasystolies, pauses, or bradycardia. If left untreated, hyperkalemia can be fatal.

25. If hyperkalemia disrupts the normal heart rhythms, the flow of blood through the heart can be slowed to the point that it permits blood clots to form. Blood clots in the heart can then lead to heart attacks, or the clots can break off and travel to the lungs where they can cause pulmonary embolism, or can travel to the brain causing stroke.

26. Indeed, during the brief time that Yasmin and Yaz have been sold in the United States, hundreds of reports of injury and death have been submitted to the FDA in association with Defendants' products.

27. In April 2002, the British Medical Journal reported that the Dutch College of General Practitioners recommended that older second generation birth control pills be prescribed in lieu of Yasmin as a result of 40 cases of venous thrombosis among women taking Yasmin.

28. In February 2003, a paper entitled *Thromboembolism Associated With the New Contraceptive Yasmin* was published in the British Medical Journal detailing a Netherlands Pharmacovigilance Centre report of five additional reports of thromboembolism where Yasmin was suspected as the cause, including two deaths.

29. In fact, in less than a five-year period, from the first quarter of 2004 through the third quarter of 2008, over 50 reports of death among users of Yasmin and Yaz have been filed with the FDA.

30. These reports include deaths associated with cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism, and stroke in women in their child bearing years.

31. Some deaths reported occurred in women as young as 17 years old.

32. Significantly, reports of elevated potassium levels are frequently included among the symptoms of those suffering death while using Yasmin or Yaz.

Over-Promotion of Yasmin and Yaz

33. Defendants market Yasmin and Yaz as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits.

34. However, because Yasmin and Yaz contain the fourth generation progestin drospirenone, they present additional health risks not associated with other birth control pills.

35. For example, prior to its sale to Defendant Bayer in 2006, Defendant Berlex Laboratories promoted Yasmin's fourth generation progestin, drospirenone, by stating, "Ask about Yasmin, and the difference a little chemistry can make."

36. In response, on July 10, 2003, the FDA objected to the characterization that drospirenone was a benefit compared to the progestin used in other combined oral contraceptives, and issued a warning letter stating, "FDA is not aware of substantial evidence of substantial clinical experience demonstrating that Yasmin is superior to

other COCs or that the drospirenone in Yasmin is clinically beneficial. On the contrary, FDA is aware of the added clinical risks associated with drospirenone [.]"

37. The FDA's warning letter continued by stating that the advertisement failed "to communicate that the potential to increase potassium is a risk" or that "increased serum potassium can be dangerous."

38. More recently, Defendants advertised that its product Yaz was indicated for treatment of premenstrual syndrome or "PMS," as opposed to the less serious condition of premenstrual dysphoric disorder or "PMDD."

39. Defendants also advertised that Yaz contained the added benefit of preventing or reducing acne.

40. In response, on October 3, 2008, the FDA issued another warning letter to Defendant Bayer for the misleading advertisement, reiterating that the marketing was misleading because it promoted Yaz for medical conditions beyond the limits of the FDA approval, and adding that "Yaz has additional risks because it contains the progestin, drospirenone … which can lead to hyperkalemia in high risk patients, which may result in potentially serious heart and health problems."

41. The FDA further warned in its October 3, 2008 letter that Yaz "does not result in completely clear skin" and that Defendants' "TV Ads misleadingly overstate the efficacy of the drug."

42. Indeed, the FDA felt Defendants' overpromotion of Yasmin was so severe that it required Bayer to run new TV advertisements to correct the previous misleading Yaz advertisements regarding acne and premenstrual syndrome.

43. Bayer ultimately agreed to spend at least $20 million on corrective TV advertisements and to submit all Yaz advertisements to the FDA for advanced screening for the next six years.

Plaintiff's Use of Yaz and Resulting Injuries

44. As a result of Defendants' claim regarding the effectiveness and safety of Yaz, Plaintiff Anne Marie Eakins medical provider prescribed and Anne Marie Eakins began using Yaz in August of 2007. Anne Marie Eakins used Yaz until November 29, 2007 when she suffered multiple bilateral pulmonary emboli.

45. As a direct and proximate result of using Yaz, Anne Marie Eakins suffered the injuries described above.

46. Prior to Plaintiff's use of Yaz, Defendants knew or should have known that use of Yaz created a higher risk of pulmonary embolism than other oral contraceptives on the market, including but not limited to second generation oral contraceptives, and that, when taken as directed, such use was unreasonably dangerous to consumers.

47. Therefore, at the time Anne Marie Eakins used Yaz Defendants knew or should have known that the use of Yaz created an increased risk to consumers of serious personal injury, including deep vein thrombosis, pulmonary embolism, heart attacks, stroke, and even death.

48. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Yaz, Defendants failed to warn Anne Marie Eakins and/or her health care providers of said serious risks before she used the product.

49. Had Anne Marie Eakins and/or her heath care providers known the risks and dangers associated with Yaz, she would not have used Yaz and would not have suffered multiple bilateral pulmonary emboli on November 29, 2007.

50. As a direct and proximate result of her use of Yaz, Plaintiff Anne Marie Eakins suffered physical injury, including but not limited to, conscious pain and suffering, as a result of her multiple bilateral pulmonary emboli.

51. As a direct and proximate result of her use of Yaz, Plaintiff Anne Marie Eakins has suffered and will continue to suffer pecuniary losses.

52. As a direct and proximate result of Plaintiff Anne Marie Eakins' use of Yaz and resulting injuries, her husband, Plaintiff Jonathan Eakins, has suffered damages and harm, including but not limited to, emotional distress and has incurred other medical expenses and other economic harm, as well as loss of consortium, services, society, companionship, love and comfort.

FIRST CAUSE OF ACTION

Strict Products Liability
Defective Manufacturing

53. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

54. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yaz.

55. The Yaz birth control pills manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants was expected to and did reach the consumer without any alterations or changes.

56. The Yaz birth control pills manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, was defective in its manufacture and construction when it left the hands of Defendants in that it deviated from product specification such that it was unreasonably dangerous to an ordinary user or consumer and posed a serious risk of injury and death.

57. As a direct and proximate result of Plaintiff's use of Yaz as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff Anne Marie Eakins suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

58. As a direct and proximate result of Plaintiff Anne Marie Eakins' use of Yaz and resulting injuries, her husband, Plaintiff Jonathan Eakins, has suffered damages and harm, including but not limited to, emotional distress and has incurred other medical expenses and other economic harm, as well as loss of consortium, services, society, companionship, love and comfort, and will continue to suffer such harm in the future.

59. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiffs' rights, so as to warrant the imposition of punitive damages.

SECOND CAUSE OF ACTION

Strict Products Liability
Design Defect

60. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

61. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yaz.

62. The Yaz birth control pills manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants was expected to and did reach the consumer without any alterations or changes.

63. The Yaz birth control pills manufactured and supplied by Defendants was defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or it was more dangerous than an ordinary consumer would expect.

64. The foreseeable risks associated with the design or formulation of the Yaz birth control pills, include, but are not limited to, the fact that the design or formulation of Yaz is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

65. As a direct and proximate result of Plaintiff's use of Yaz as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff Anne Marie Eakins suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

66. As a direct and proximate result of Plaintiff Anne Marie Eakins' use of Yaz and resulting injuries, her husband, Plaintiff Jonathan Eakins, has suffered damages and harm, including but not limited to, emotional distress and has incurred other medical expenses and other economic harm, as well as loss of consortium, services, society, companionship, love and comfort, and will continue to suffer such harm in the future.

67. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiffs' rights, so as to warrant the imposition of punitive damages.

THIRD CAUSE OF ACTION

Strict Products Liability
Defect Due to Inadequate Warning

68. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

69. The Yaz birth control pills manufactured and supplied by Defendants was defective due to inadequate warning or instruction and was unreasonably dangerous to the ordinary user or consumer because Defendants knew or should have known that the product created significant risks of serious bodily harm and death to consumers and they failed to adequately warn consumers and/or their health care providers of such risks.

70. The Yaz birth control pills manufactured and supplied by Defendants was defective due to inadequate post-marketing warning or instruction and was unreasonably dangerous to the ordinary user or consumer because, after Defendants knew or should have known of the risk of serious bodily harm and death from the use of Yaz, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and death.

71. As a direct and proximate result of Plaintiff's use of Yaz as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants,

Plaintiff Anne Marie Eakins suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

72. As a direct and proximate result of Plaintiff Anne Marie Eakins' use of Yaz and resulting injuries, her husband, Plaintiff Jonathan Eakins, has suffered damages and harm, including but not limited to, emotional distress and has incurred other medical expenses and other economic harm, as well as loss of consortium, services, society, companionship, love and comfort, and will continue to suffer such harm in the future.

73. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiffs' rights, so as to warrant the imposition of punitive damages.

FOURTH CAUSE OF ACTION

Negligence

74. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

75. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of Yaz into the stream of commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events.

76. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Yaz into interstate commerce in that Defendants knew or

should have known that the product caused such significant bodily harm or death and was not safe for use by consumers.

77. Defendants also failed to exercise ordinary care in the labeling of Yaz and failed to issue to consumers and/or their health care providers adequate warnings of the risk of serious bodily injury or death due to the use of Yaz.

78. Despite the fact that Defendants knew or should have known that Yaz posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market Yaz for use by consumers.

79. Defendants knew or should have known that consumers such as Plaintiff Anne Marie Eakins would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

80. As a direct and proximate result of Defendants' negligence, Plaintiff Anne Marie Eakins suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

81. As a direct and proximate result of Plaintiff Anne Marie Eakins' use of Yaz and resulting injuries, her husband, Plaintiff Jonathan Eakins, has suffered damages and harm, including but not limited to, emotional distress and has incurred other medical expenses and other economic harm, as well as loss of consortium, services, society, companionship, love and comfort, and will continue to suffer such harm in the future.

82. Defendants' conduct as described above, including but not limited to its failure to adequately test Yaz, to provide adequate warnings, and its continued manufacture, sale and marketing of the product when it knew or should have known of the serious health risks it created, evidences malicious actions, aggravated or egregious

fraud, and/or intentional disregard of the rights of Plaintiffs, so as to warrant the imposition of punitive damages.

FIFTH CAUSE OF ACTION

Negligent Misrepresentation and/or Fraud

83. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

84. Defendants are the manufacturers, designers, distributors, sellers or suppliers of Yaz and made representations to Plaintiff and her physician regarding the character or quality of Yaz for guidance in their decision to select Yaz.

85. Specifically, Defendants represented that their product was just as safe or safer, and just as effective or more effective, than other birth control products on the market.

86. Defendants' representations regarding the character or quality of Yaz were untrue.

87. Defendants had actual knowledge based upon studies, published reports and clinical experience that its product Yaz created an unreasonable risk of serious bodily injury and death to consumers, or should have known such information.

88. Defendants negligently and/or intentionally misrepresented or omitted this information in its product labeling, promotions and advertisements and instead labeled, promoted and advertised its product as safer and more effective than other types of oral contraceptives in order to avoid losses and sustain profits in its sales to consumers.

89. In supplying the false information, Defendants failed to exercise reasonable care or competence in obtaining or communicating information to Plaintiff and her physician.

90. Plaintiff Anne Marie Eakins and her physician reasonably relied to her detriment upon Defendants' misrepresentations and/or omissions in its labeling, advertisements, and promotions concerning the serious risks posed by the product. Plaintiff Anne Marie Eakins reasonably relied upon Defendants' representations to her and/or her health care providers that Yaz was safer than other types of oral contraceptives for human consumption and/or use and that Defendants' labeling, advertisements and promotions fully described all known risks of the product.

91. As a direct and proximate result of Defendants' negligent and/or intentional misrepresentations or omissions, Plaintiff Anne Marie Eakins suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

92. As a direct and proximate result of Plaintiff Anne Marie Eakins' use of Yaz and resulting injuries, her husband, Plaintiff Jonathan Eakins, has suffered damages and harm, including but not limited to, emotional distress and has incurred other medical expenses and other economic harm, as well as loss of consortium, services, society, companionship, love and comfort, and will continue to suffer such harm in the future.

93. Defendants' actions and omissions as identified in this Complaint demonstrate malicious actions, aggravated or egregious fraud, and/or intentional disregard of Plaintiffs' rights so as to warrant the imposition of punitive damages.

WHEREFORE, Plaintiff prays for relief as follows:

1. Compensatory and punitive damages in excess of the jurisdictional amount, including, but not limited to non-economic damages in excess of $350,000.00;

2. Medical expenses and other economic damages in an amount to be determined at trial of this action;

3. Attorneys' fees, expenses, and costs of this action;

4. Punitive damages in excess of twice the compensatory damages award;

5. Such further relief as this Court deems necessary, just, and proper.

Dated: July 10, 2009

Respectfully submitted,

/s/ Janet G. Abaray

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JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

/s/ Janet G. Abaray
Janet G. Abaray (0002943)

IN THE U.S. DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

BRENDA ELLYSON
26 Jenning Ave.
Cuyahoga Falls, OH 44221

Plaintiff,

v.

BAYER CORPORATION
c/o CSC-Lawyers Incorporating Service (Corporation Service Company)
50 W. Broad St. Suite 1800
Columbus, OH 43215

and

BAYER HEALTHCARE LLC,
c/o CSC-Lawyers Incorporating Service (Corporation Service Company)
50 W. Broad St. Suite 1800
Columbus, OH 43215

and

BAYER PHARMACEUTICALS CORPORATION,
c/o CSC-Lawyers Incorporating Service (Corporation Service Company)
50 W. Broad St. Suite 1800
Columbus, OH 43215

and

CASE NO.

JUDGE

COMPLAINT WITH JURY DEMAND ENDORSED HEREON

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Michelle L. Kranz (0062479)
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and

BERLEX LABORATORIES, INC.
c/o CSC-Lawyers Incorporating Service (Corporation Service Company)
340 Changebridge Road
Montville, NJ 07045

and

BERLEX, INC.
c/o CSC-Lawyers Incorporating Service (Corporation Service Company)
340 Changebridge Road
Montville, NJ 07045

and

JOHN DOE MANUFACTURERS A-Z
[Real Names and Addresses Unknown]

and

JOHN DOE DISTRIBUTORS A-Z
[Real Names and Addresses Unknown]

Defendants.

Now comes Plaintiff, by and through the undersigned counsel, and for her Complaint hereby avers and states as follows:

NATURE OF THE ACTION

1. This is an action for strict product liability (Ohio R.C. § 2307.71 *et seq.*), fraudulent misrepresentation, civil conspiracy and commercial bribery, loss of consortium, and punitive damages brought by Plaintiff for damages associated with her ingestion of the pharmaceutical drug YAZ, an oral contraceptive developed, designed, licensed, manufactured, distributed, sold, and/or marketed by Defendants.

2. As a result of the ingestion of YAZ, Plaintiff suffered injuries to her person including, but not limited to, deep vein thrombosis.

THE PARTIES

3. Plaintiff Brenda Ellyson, (herein "Plaintiff"), resides in the city of Cuyahoga Falls, Summit County, Ohio.

4. Defendant BAYER CORPORATION is, and at all times relevant was, a corporation organized under the laws of the State of Indiana with its headquarters and principal place of business at 100 Bayer Rd., Pittsburgh, Pennsylvania 15205.

5. At all times relevant, Defendant BAYER CORPORATION was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

6. Defendant BAYER HEALTHCARE LLC, is, and at times relevant was, a limited liability corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 100 Bayer Road, Pittsburg, PA 15205.

7. At all times relevant, Defendant BAYER HEALTHCARE LLC was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing,

and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

8. Defendant BAYER HEALTHCARE LLC is wholly owned by Defendant BAYER CORPORATION.

9. Defendant BAYER PHARMACEUTICALS CORPORATION is, and at times relevant was, a corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 1400 Morgan Lane, West Haven, Connecticut.

10. At all times relevant, Defendant BAYER PHARMACEUTICALS CORPORATION was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

11. As of January 1, 2008, Defendant BAYER PHARMACEUTICALS CORPORATION was merged into Defendant BAYER HEALTHCARE PHARMACEUTICALS INC.

12. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC., is and at times relevant was, a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

13. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc., and is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc.

14. At all times relevant, Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

15. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. applied for and received U.S. marketing approval of Yasmin and YAZ by the FDA, and is the holder of approved New Drug Application ("NDA") for Yasmin and YAZ.

16. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. are, and at all times relevant were, foreign corporations with their headquarters and principal places of business at Montville, New Jersey and with a post office address of P.O. Box 1000, Montville, New Jersey, 07045 and places of business located at 6 West Belt Road, Wayne, New Jersey 07470.

17. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. were integrated into Bayer HealthCare AG and operates as an integrated specialty pharmaceuticals business under the new name, Defendant Bayer Healthcare Pharmaceuticals, Inc.

18. At all times relevant, Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

19. Defendants John Doe Manufacturers A-Z (fictitious-name designations of one or more individuals, partnerships, corporations, and/or other entities whose actual identities have yet to be determined) at all times relevant hereto were in the business of developing, researching,

selling, distributing, designing, manufacturing, testing, evaluating, licensing, labeling, marketing, and/or placing, either directly or indirectly through third parties or related entities, pharmaceutical drugs including Yasmin and YAZ into interstate commerce, including in the Northern District of Ohio, and derived substantial revenue from these activities.

20. Defendants John Doe Distributors A-Z (fictitious-name designations of one or more individuals, partnerships, corporations, and/or other entities whose actual identities have yet to be determined) at all times relevant hereto were in the business of developing, researching, selling, distributing, designing, manufacturing, testing, evaluating, licensing, labeling, marketing, and/or placing, either directly or indirectly through third parties or related entities, pharmaceutical drugs including Yasmin and YAZ into interstate commerce, including in the Northern District of Ohio, and derived substantial revenue from these activities.

21. Defendants Bayer Corporation, Bayer Healthcare LLC, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Berlex Laboratories, Inc. and Berlex, Inc., and John Doe Manufacturers and Distributors A-Z shall be referred to herein individually by name or jointly as "Defendants."

22. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

23. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in interest, aider and abettor, co-conspirator and joint venturer of each of the remaining Defendants herein and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture.

JURISDICTION AND VENUE

24. This Court has jurisdiction over this action pursuant to 28 U.S.C.A. § 1332, as there is complete diversity of citizenship between Plaintiff and Defendants, and the amount in controversy exceeds $75,000, exclusive of interest and costs.

25. Venue is proper in the Northern District of Ohio pursuant to 28 U.S.C.A. § 1391, as a substantial part of the events giving rise to these claims occurred within this district, including the prescription and use of YAZ, as well as Plaintiff's resulting injuries.

26. The Court has personal jurisdiction over Defendants consistent with the Ohio and United States Constitution pursuant to Ohio R. C. § 2307.382(4) because Defendants caused tortious injury in Ohio by an act or omission outside Ohio by virtue of Defendants' regularly conducted business in Ohio from which they respectively derive substantial revenue. Defendants do substantial business in the State of Ohio and within the Northern District of Ohio, advertise in this district, and receive substantial compensation and profits from sales of Yasmin and YAZ within this District.

27. Defendants expected or should have expected that their business activities could or would have consequences within the State of Ohio, as well as throughout the United States.

FACTS

Yasmin and YAZ Background

28. Yasmin, (a predecessor to YAZ), known generically as drospirenone and ethinyl estradiol, is a combination birth control pill originally developed by Defendant BERLEX LABORATORIES, INC. and/or Defendant BERLEX, INC containing the hormones estrogen and progestin.

29. The estrogen is ethinyl estradiol and the progestin is drospirenone, (3 mg of

drospirenone and 0.03 mg of ethinyl estradiol per tablet).

30. Combination birth control pills are referred to as combined hormonal oral contraceptives.

31. Yasmin was approved by the FDA in April, 2001.

32. In 2006, Bayer acquired Defendant BERLEX LABORATORIES, INC. and/or Defendant BERLEX, INC, and began marketing an almost identical drug, YAZ (which contains 3 mg of drospirenone and 0.02 mg of ethinyl estradiol per tablet).

33. The difference between YAZ/Yasmin and other birth control pills on the market is that drospirenone has never before been marketed in the United States and is unlike other progestins available in the United States.

34. Shortly after the introduction of combined oral contraceptives in the 1960s, doctors and researchers found that women using birth control pills had a higher risk of blood clots, heart attacks and strokes than women not using the pill. As a result, the various brands of birth control pills were reformulated to reduce the amounts of estrogen. As the amounts of estrogen levels reduced, so too did the risk of blood clots, heart attacks and strokes.

35. During this time, new progestins were being developed, which became known as "second generation" progestins (e.g. lovenorgestrel). These second generation progestins, when combined with the lower amounts of the estrogen, ethinyl estradiol, helped to reduce the risk of blood clots, heart attacks and strokes and were considered safer for women.

36. During the 1990s, new "third generation" progestins were developed. Unfortunately, these "third generation" progestins (e.g. gestodene and desogestrel) have been associated with a greater risk of blood clots in the deep veins (deep vein thrombosis or "DVT") and lungs (pulmonary embolism or "PE"). As a result of this increased risk of blood clots, the FDA has

required that products containing third generation progestins include a warning of the potentially increased risk of thrombosis.

37. Yasmin and YAZ contain the same estrogen component, ethinyl estradiol, that has been used in the lower dose birth control pills for decades.

38. However, drospirenone is a new type of progestin and is considered a "fourth generation" progestin. No other birth control pills contain drospirenone, except for a recently approved generic version of Yasmin and YAZ marketed under the trade name, Ocella.

39. Since drospirenone in birth control is new, there are not decades of data available to support its safe use as there are with second generation progestins. Studies that were done prior to FDA approval, however, indicate that drospirenone has certain effects that are different from those of traditional second generation progestins, and potentially more dangerous.

40. One possible mechanism of action is that drospirenone causes an increase in potassium levels in the blood, which can lead to a condition known as hyperkalemia if the potassium levels become too high.

41. Hyperkalemia can cause heart rhythm disturbances, such as extrasystolies, pauses or bradycardia. If left untreated, hyperkalemia can be fatal.

42. If hyperkalemia disrupts the normal heart rhythms, the flow of blood through the heart can be slowed to the point that it permits blood clots to form, including deep vein thrombosis. Blood clots in the heart can then lead to heart attacks, or the clots can break off and travel to the lungs where they can cause pulmonary embolism, or can travel to the brain causing stroke.

43. Another effect is a substantially increased risk of gallbladder complications.

44. During the brief time that Yasmin and YAZ have been sold in the United States,

hundreds of reports of injury and death have been submitted to the FDA in association with Defendants' products.

45. In April 2002, the British Medical Journal reported that the Dutch College of General Practitioners recommended that older second generation birth control pills be prescribed in lieu of Yasmin as a result of 40 cases of venous thrombosis among women taking Yasmin.

46. In February 2003, a paper entitled *Thromboembolism Associated With the New Contraceptive Yasmin* was published in the British Medical Journal detailing a Netherlands Pharmacovigilance Centre report of five additional reports of thromboembolism where Yasmin was suspected as the cause, including two deaths.

47. In fact, in less than a five-year period, from the first quarter of 2004 through the third quarter of 2008, over 50 reports of death among users of Yasmin and YAZ have been filed with the FDA.

48. These reports include deaths associated with cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism and stroke in women in their child bearing years.

49. Some deaths reported occurred in women as young as 17 years old.

50. Significantly, reports of elevated potassium levels are frequently included among the symptoms of those suffering death while using Yasmin or YAZ.

Defendants' Over-Promotion, Fraud and Failures Regarding Yasmin and YAZ

51. Defendants market Yasmin and YAZ as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits.

52. However, because Yasmin and YAZ contain the fourth generation progestin drospirenone, they present additional health risks not associated with other birth control pills.

53. Defendants have been warned at least three times by the FDA; in 2003, 2008 and

2009, for misleading the public through the use of ads which overstate the efficacy of YAZ and/or its predecessor Yasmin, and minimize serious risks associated with the drug.

54. Indeed, the FDA felt Defendants' over-promotion of YAZ was so severe that it required Bayer to run new TV advertisements to correct the previous misleading YAZ advertisements.

55. Bayer ultimately agreed to spend at least $20 million on corrective TV advertisements and to submit all YAZ advertisements to the FDA for advanced screening for the next six years.

56. Defendants ignored the correlation between the use of Yasmin and YAZ and increased thrombosis formation despite the wealth of scientific information available.

57. Upon information and belief, Defendants knew or should have known about the correlation between the use of Yasmin and YAZ and a prothrombotic effect and still promoted, sold, advertised, and marketed the use of Yasmin and YAZ.

58. Defendants falsely and fraudulently represented to the medical and healthcare community, to Plaintiff, the FDA, and the public in general, that Yasmin and YAZ had been tested and was found to be safe and/or effective for its indicated use.

59. These false representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, dispense and/or purchase Yasmin and YAZ for use as a contraceptive, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of Plaintiff.

60. Defendants knew and were aware or should have been aware that Yasmin and YAZ had not been sufficiently tested, was defective in its design and testing, and/or lacked adequate

and/or sufficient warnings.

61. Defendants knew or should have known that Yasmin and YAZ had a potential to, could, and would cause severe and grievous injury and death to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate and/or down-played warnings.

62. In representations to Plaintiff, her healthcare providers, and/or the FDA, Defendants also fraudulently concealed and intentionally omitted the following material information:

a. That Yasmin/YAZ is not as safe as other available contraceptives;

b. That the risks of adverse events with Yasmin/YAZ (drospirenone and ethinyl estradiol) was higher than those of other available contraceptives;

c. That the risks of adverse events with Yasmin/YAZ was not adequately tested and/or known by Defendants;

d. Plaintiff was put at risk of experiencing serious and dangerous side effects including, but not limited to, deep vein thrombosis, as well as other severe and personal injuries, physical pain, and mental anguish;

e. That patients needed to be monitored more regularly than normal while using Yasmin/YAZ; and/or

f. That Yasmin/YAZ was designed, tested, manufactured, marketed, produced, distributed and advertised negligently, defectively, fraudulently and improperly.

63. Defendants were under a duty to disclose to Plaintiff and her physicians, hospitals, healthcare providers and/or the FDA the defective nature of Yasmin and YAZ.

64. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to person who used Yasmin and YAZ, including Plaintiff.

65. Defendants made the misrepresentations and/or actively concealed information concerning the safety and efficacy of Yasmin and YAZ with the intention and specific desire that

the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, would rely on such in selecting Yasmin and YAZ as a contraceptive.

66. Defendants made these misrepresentations and/or actively concealed information concerning the safety and efficacy of Yasmin and YAZ in their labeling, advertising, product inserts, promotional material or other marketing efforts.

67. The misrepresentations of and/or active concealment by Defendants were perpetuated directly and/or indirectly by Defendants, its sales representative, employees, distributors, agents and/or detail persons.

68. Defendants knew that Plaintiff, her healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Yasmin and YAZ, as set forth herein.

69. The misrepresentations of and/or active concealment by Defendants constitute a continuing tort. Indeed, through Defendants' product inserts, Defendants continue to misrepresent the potential risks and serious side effects associated with the use of Yasmin and YAZ.

70. Moreover, Defendants had a post-sale duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, about the potential risks and serious side effects associated with the use of YAZ in a timely manner, yet they failed to provide such warning.

FACTS REGARDING PLAINTIFF BRENDA ELLYSON

71. Plaintiff Brenda Ellyson was prescribed YAZ by her health care provider.

72. Plaintiff justifiably relied on and/or was induced by the misrepresentations and/or active concealment of Defendants to purchase and ingest YAZ to her detriment.

73. As a result of using Defendants' product YAZ, on or about June 23, 2009, Plaintiff sustained serious and life-threatening side effects including, but not limited to, deep vein thrombosis (DVT), future thromboembolic events, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses, the need for lifelong medical treatment, monitoring and/or medications, and the fear of developing any of the above named health consequences.

CAUSES OF ACTION

COUNTS I-IV

Defective Manufacturing/Construction (R.C. § 2307.74)
Defective Design/Formulation (R.C. § 2307.75)
Defective Warning/Instruction (R.C. § 2307.76)
Defective Due to Nonconformity with Representation (R.C. § 2307.77)

74. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

75. At all times relevant to this action, Defendants were the manufacturers, as defined at Revised Code § 2307.71, and distributors, which designed, produced, created, made, constructed and/or assembled the drugs, Yasmin and YAZ, that were placed into the stream of commerce.

76. The Yasmin and YAZ birth control pills were expected to and did reach the ultimate users, including Plaintiff, without substantial change in the condition they were sold.

77. The Yasmin and YAZ birth control pills manufactured, designed, sold, distributed, supplied, promoted and/or place in the stream of commerce by Defendant were defective in their:

a. Manufacture and construction pursuant to the provisions of Ohio Revised Code § 2307.74;

b. Design pursuant to the provisions of Ohio Revised Code § 2307.75;

c. Inadequate warning or instruction pursuant to the provisions of Ohio Revised Code § 2307.76, and/or

d. Failure to conform, when it left the control of Defendants, to their representations, pursuant to the provisions of Ohio Revised Code § 2307.77.

78. Specifically, Defendants' failures, which permitted defective drugs, Yasmin and YAZ, to be placed in the stream of commerce, include, but are not necessarily limited to:

a. Defendants' failure to exercise reasonable care in the manufacture, design and testing of Yasmin and YAZ;

b. Defendants' failure to include adequate warnings that would alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, of the substantially increased risks and serious side effects of the drug;

c. Defendants' failure to adequately and properly test and inspect the drug before placing the drug on the market;

d. Defendants' failure to conduct sufficient testing and inspection of the drug which, if properly performed, would have shown that the drug had serious increased side effects, including, but not limited to, deep vein thrombosis, and other serious and life threatening side effects;

e. Defendants' failure to adequately warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff of the potential risks and other serious side effects associated with the drug, including, among other things, deep vein thrombosis and other serious and life threatening side effects;

f. Defendants' failure to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risks associated with the use of the drug;

g. Defendants' failure to recall and/or remove the drug from the stream of commerce despite the fact that Defendants knew or should have known of the defective and unreasonably dangerous nature of the drug, including the significant health risks associated with the use of the drug; and

h. Defendants' encouragement of misuse and overuse while failing to disclose the side effects of the drug to the medical, pharmaceutical and/or scientific communities, and users and/or consumers, including Plaintiff, in order to maximize profit from sales.